PRVD2009-10

Proposed Re-evaluation Decision

Dodemorph-Acetate

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Overview

Proposed Re-evaluation Decision for Dodemorph-Acetate

After a re-evaluation of the fungicide dodemorph-acetate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing to phase out the sale and use of dodemorph-acetate products in Canada.

An evaluation of available scientific information found that, under the current conditions of use, the human health risks estimated for dodemorph-acetate do not meet current standards. In particular, there are risk concerns for postapplication workers in greenhouse and field rose production that cannot be sufficiently mitigated based on current information. To address some of the uncertainties in the occupational risk assessment, it is possible that additional data and use information could be submitted. Any relevant information provided during the Proposed Re-evaluation Decision consultation period will be considered prior to a final decision.

The PMRA's pesticide re-evaluation program considers the potential risks as well as value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure. Re-evaluation draws on data from the registrant or published scientific reports, information from other regulatory agencies and any other relevant information available.

This proposal affects all end-use products containing dodemorph-acetate registered in Canada. Pending the outcome of this re-evaluation, initial label statements to address environmental risk are included in this document; however, additional statements to protect workers could be recommended as part of a final decision, if appropriate. Once the final re-evaluation decision is made, registrants will be instructed on how to implement the regulatory decision.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for dodemorph-acetate and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of dodemorph-acetate.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration[2]. The Act also requires that products have value[3] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a re-evaluation decision on dodemorph-acetate, the PMRA will consider all comments received from the public in response to this consultation document[4]. The PMRA will then publish a Re-evaluation Decision[5] on dodemorph-acetate, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What is Dodemorph-Acetate?

Dodemorph-acetate is a Resistance Management Group Number 5 (amines) fungicide used to control powdery mildew on greenhouse- and field-grown roses. It is only available as commercial products and is applied solely by ground application equipment. In Canada, it is estimated that a total of about 153 ha of roses are grown (greenhouse: 23 ha and outdoor: 130 ha).

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2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's *(a)* efficacy; *(b)* effect on host organisms in connection with which it is intended to be used; and *(c)* health, safety and environmental benefits and social and economic impact."

4 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

5 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Dodemorph-Acetate Affect Human Health?

Risks to human health via dietary or occupational exposure from application are not of concern; however, postapplication occupational risks are of concern.

Potential exposure to dodemorph-acetate may occur through the diet (drinking water), when handling and applying the product, or when entering treated areas. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are exposed in the diet or via occupational application when dodemorph-acetate products are used according to label directions. However, occupational exposure levels from postapplication activities are expected to exceed those of other activities and do not achieve the target margins of exposure.

Dodemorph-acetate is of low oral toxicity to rats and low dermal toxicity to rabbits. The requirement for an acute inhalation toxicity study has been waived due to the inability of the active ingredient to be adequately aerosolized for test purposes and due to the anticipated irritative properties of the compound. Dodemorph-acetate is extremely irritating to the skin, severely irritating to the eye and is a potential skin sensitizer.

The target organ of dodemorph-acetate is the liver, with effects including increases in liver weights and various histopathological findings of the liver being observed at doses at or above doses causing body-weight effects and/or vomiting in test animals.

There was no evidence that dodemorph-acetate was genotoxic or evidence of carcinogenicity in mice or in male rats. A slight increase in rare ovarian adenocarcinomas was observed in female rats exposed to high doses of dodemorph-acetate for two years.

When dodemorph-acetate was given to pregnant rats, a shortened gestation period was observed in the dams, with delays in pup development, increases in prenatal mortality, as well as foetal malformations. Due to the nature of these endpoints and their potential prenatal and postnatal implications, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to dodemorph-acetate.

Residues in Water and Food

Dietary risks from water are not of concern.

As dodemorph-acetate is not registered for use on food commodities, the dietary risk assessment considered exposure from drinking water only.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

One-day (acute) and long-term (chronic) drinking water exposure estimates were determined for the general population and different subpopulation groups representing different ages, genders and reproductive status. Dodemorph-acetate residues in drinking water were modeled with conservative assumptions and were considered to be a high-end estimate.

The acute and chronic exposure estimates from water were below the level of concern for all population groups.

Risks in Residential and Other Non-Occupational Environments

As there are no registered residential uses of dodemorph-acetate, exposure and risk to people in and around residential areas is expected to be negligible.

Occupational Risks from Handling Dodemorph-Acetate

Occupational risks are not of concern for mixer/loaders/applicators.

Risk estimates associated with mixing, loading and application activities are not of concern and additional personal protective equipment are not required beyond what is currently specified on the label.

Postapplication risks to workers are of concern.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Postapplication exposure and risk for workers entering treated greenhouses and fields are of concern and cannot be sufficiently mitigated based on current information.

The risk assessment was conducted according to current standards and included a number of uncertain assumptions made in the absence of data. The generation of additional data would be required to address uncertainties in the risk assessment.

Environmental Considerations

What Happens When Dodemorph-Acetate Is Introduced Into the Environment?

Dodemorph-acetate poses a potential risk to certain terrestrial and aquatic organisms; therefore, additional risk-reduction measures need to be observed.

Although it is primarily used in greenhouses, there is potential environmental exposure from application of dodemorph-acetate to field-grown roses and runoff from some types of greenhouse structures.

Dodemorph-acetate is a not a persistent substance in the soil and water. Phototransformation is rapid in both media and is the dominant mode of transformation in soils, except under acidic conditions. Biotransformation is the dominant mode of transformation in the water column and sediment.

Dodemorph-acetate was not found to be a risk to bees or earthworms. However, it does pose a potential risk to beneficial arthropods. Both birds and mammals were found to be at risk if they consume food sources sprayed with dodemorph-acetate. However, birds were not found to be at risk from consuming food sources present off-field that was contaminated with spray drift, although mammals were found to be at risk. However, given the mobile nature of mammals, resulting in their reduced exposure, the risk from spray drift of dodemorph-acetate is not expected to be a concern for mammals or birds. Dodemorph-acetate is not a risk to most aquatic organisms from runoff or spray drift, with the exception of amphibians from spray drift. The risk to amphibians can be mitigated through the use of spray buffer zones. Additional risk-reduction measures such as buffer zones and advisory/precautionary label statements are recommended.

Value Considerations

What is the Value of Dodemorph-Acetate?

Dodemorph-acetate provides good control of powdery mildew on greenhouse and field-grown roses.

Dodemorph-acetate has been identified as having a low to medium risk for resistance development. It is an important tool to Canadian rose growers for powdery mildew resistance management as it can be used in rotation with other existing chemicals registered for the same use. In Canada, it is estimated that a total of about 153 ha of roses are grown (greenhouse: 23 ha and outdoor: 130 ha).

Measures to Minimize Risk

To address the estimated risks, the PMRA is currently proposing to phase out the sale and use of dodemorph-acetate products in Canada. Pending the outcome of this re-evaluation, initial label statements to address environmental risk are included in this document. However, additional statements to protect workers could be recommended as part of a final decision, if appropriate.

Additional Key Risk-Reduction Measures

Human Health

Additional risk-reduction measures are not being proposed at this time.

Environment

To reduce the release of dodemorph-acetate into the environment for the protection of terrestrial and aquatic habitats that may contain sensitive species, the PMRA is proposing:

- Additional advisory statements to protect non-target species
- Buffer zones for aquatic habitats

What Additional Scientific Information is Being Requested?

Additional data could be submitted to address uncertainties in the postapplication occupational exposure and risk assessment. Additional data and use information, together with suggestions to reduce worker exposure and information on the impact of the proposed decision, are being requested from the registrant, provincial advisors and users (i.e. the rose production industry), for example:

Human Health

- Adequate dodemorph-acetate dislodgeable foliage residue (DFR) data for greenhouse and field roses
- Additional dermal absorption data to further refine the dermal absorption factor
- Additional information on the dodemorph-acetate use pattern, including typical rates, typical number of applications per season, typical work day durations, typical worker activities after treatment, typical work clothing worn when handling roses
- Data supporting the feasibility of additional protective clothing and/or other mitigation measures suggested by industry for postapplication worker activities
- Dodemorph-acetate air concentration data in greenhouses following application with relevant equipment

Value

- Quantitative and/or qualitative data on the economic and social importance of dodemorph-acetate to rose production
- Feedback on the viability of alternative chemical and non-chemical pest management practices for this use

Next Steps

Before making a re-evaluation decision on dodemorph-acetate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision document, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Other Information

When the re-evaluation decision is made, the PMRA will publish an Evaluation Report on dodemorph-acetate in the context of this re-evaluation decision (based on the Science Evaluation section of this consultation document). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

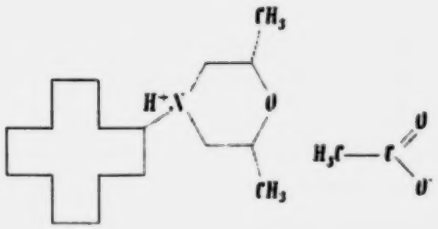
1.0 Introduction

Dodemorph-acetate is a systemic fungicide with protective and curative action. It belongs to Resistance Management Group Number 5 (amines, Sterol Biosynthesis Inhibitors (SBI): Class II). This fungicide is registered in Canada for the control of powdery mildew on greenhouse- and field-grown roses. It acts by inhibiting an isomerase and a reductase enzyme in sterol biosynthesis in fungal membranes.

Following the re-evaluation announcement for dodemorph-acetate, BASF Canada Inc., the registrant of technical grade dodemorph-acetate and the primary data provider in Canada, indicated continued support for all uses included on the label of the Commercial Class end-use product, Meltatox Powdery Mildew Fungicide.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Active Substance

Active substance	Dodemorph-acetate
Function	Fungicide
Chemical names	
1. International Union of Pure and Applied Chemistry (IUPAC)	4-cyclododecyl-2,6-dimethylmorpholinium acetate
2. Chemical Abstracts Service (CAS)	Not available
CAS Registry Number	31717-87-0
Molecular formula	$C_{20}H_{39}NO_3$
Molecular weight	341.5
Structural formula	
Registration number	19334
Purity	96% nominal (limits: 91–99%)
Basic manufacturer(s)	BASF Aktiengesellschaft, Germany

Identity of relevant impurities of toxicological, environmental and/or other significance:
Based on the manufacturing process and the starting materials used, impurities of human health or environmental concern as identified in Section 2.13.4 of DIR98-04 and TSMP Track 1 substances as identified in Appendix II of DIR99-03 are not expected to be present in the product.

2.2 Physicochemical Properties of Active Substance and Interpretation

Property	Result
Vapour pressure at 25°C	12 mPa[1]
Henry's law constant	0.008 Pa m^3mol^{-1}[1]
Ultraviolet–visible spectrum	Not expected to absorb UV at $\lambda > 220$ nm (λ max = 206.3 nm)[2]
Solubility in water	**pH** **solubility (mg/L)**[1] 5 736 7 520 9 2.29
n-Octanol–water partition coefficient (K_{ow})	**pH** **log K_{ow}**[1] 5 2.52 9 4.23
Dissociation constant (pK_a) in water/methanol 80/20 (v/v) at 20°C	pKa= 8.53[2]

1 From *e-Pesticide Manual*, 13th Edition, Volume 3.1, 2004–2005, entry # 288.

2 From Chemical File, DOM-BAZS-1, Additional Re-Evaluation, Dodemorph-acetate, submission 2003-0561, Volume 1 of 1, DACO 2.1–2.16, October 2003.

2.3 Description of Registered Dodemorph-Acetate Uses

Appendix I lists the dodemorph-acetate products that are registered under the authority of the *Pest Control Products Act*. Appendix II lists the uses for which dodemorph-acetate is presently registered. The uses were supported by the registrant at the time of the initiation of re-evaluation and were therefore considered in the health and environmental risk assessments of dodemorph-acetate. The uses were not added to the use pattern as a response to a User Requested Minor Use Label Expansion (URMULE).

Registrant-supported uses of dodemorph-acetate belong to the following use-site categories:

- Greenhouse Non-food Crops (Use-site Category 6): greenhouse-grown roses; and
- Ornamental Outdoors (Use-site Category 27): field-grown roses.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Dodemorph-acetate is a morpholine fungicide. A review of the toxicology database for dodemorph-acetate was last conducted in 1975. Since then, a substantial number of toxicology studies have been submitted. Most studies considered for risk assessment, including those investigating reproductive, developmental and long-term toxicity, have been conducted recently (1992–2003) according to international guidelines and good laboratory practice (GLP). Some studies identified in the database predate good laboratory practice and may not meet international guidelines; however, the review of these studies suggests that the impact on the overall assessment is minimal. The results of the toxicological studies present consistent target organs and similar effect levels for endpoints of concern.

Toxicokinetic studies in rats indicate rapid absorption and excretion at lower (10 mg/kg bw) doses of dodemorph-acetate, with the rate of absorption and excretion decreasing substantially at high doses (1000 mg/kg bw). Peak blood concentrations were achieved at 6 hours following exposure via oral gavage at the low dose, but were not reached until 48 hours following the high dose exposure. At all doses, an equal fraction of dodemorph-acetate metabolites are excreted through urinary and fecal excretion. The metabolite profile for both urinary and fecal excretory products is similar, with the majority of metabolites being polar. The parent compound was not identified in the urine, with a small amount (not quantified) identified in fecal excretion indicating extensive metabolism.

Dodemorph-acetate is of low oral toxicity to rats and low dermal toxicity to rabbits. The requirement for an acute inhalation toxicity study has been waived due to the inability of the active ingredient to be adequately aerosolized for test purposes and due to the anticipated irritative properties of the compound. Dodemorph-acetate is extremely irritating to the skin, severely irritating to the eye and is a potential skin sensitizer.

The target organ of dodemorph-acetate is the liver with effects also being observed in the lungs following repeat dose exposure. In repeat dose rat and mouse assays, body weight and body-weight gains were consistently affected at doses at or below that of liver effects. At higher doses (≥160 mg/kg bw/day), increases in absolute and relative liver weights are observed, often accompanied by various histopathological findings of the liver including eosinophilic foci, fatty changes, centrilobular hypertrophy, peribiliary fibrosis and proliferation of the biliary duct. Effects on the lungs of female rats have been observed following long-term exposure at greater than 222 mg/kg bw/day and included increased relative weights, mineralization, an increased presence of foamy macrophages and alveolar hyperplasia.

Two supplementary studies in dogs (28-day toxicity, 90-day toxicity) and an acceptable one-year toxicity study were provided by the registrant. In all three studies, postdosing salivation (≥25 mg/kg bw/day), vomiting (≥10 mg/kg bw/day) and decreases in body-weight gain (≥10 mg/kg bw/day) were observed. In the one-year assay, superficial erosion of the stomach accompanied by inflammation was observed at higher doses in the animals (≥25 mg/kg bw/day), suggesting that the vomiting may have been secondary to gastric irritation.

The target organ in dogs was the liver, with vacuolar degeneration, peribiliary fibrosis, biliary hyperplasia and increases in lipofuscin being observed (≥25 mg/kg bw/day) in the one-year assay. Increases in relative liver weight were observed at doses exceeding those resulting in histopathological observations.

Acceptable repeat dose studies from the dermal and inhalation routes of exposure were not available.

A series of in vivo and in vitro genotoxicity studies investigating the mutagenic and clastogenic potential of dodemorph-acetate have been provided. The data indicate that dodemorph-acetate does not cause mutagenicity or clastogenicity.

Dodemorph-acetate demonstrated no evidence of carcinogenic potential in mice following long-term dosing. In the chronic carcinogenicity study in rats, a slight increase in rare ovarian adenocarcinomas was identified at the highest dose tested (222 mg/kg bw/day). The occurrence of ovarian adenocarcinomas in carcinogenicity studies in rats is rare and occurred in the absence of preneoplastic lesions.

A supplementary one-generation reproductive toxicity study and a guideline two-generation reproductive toxicity assay were available. In the two-generation reproductive toxicity assay, a decrease in gestation interval was observed at 64 mg/kg bw/day and greater. Toxicity to the parental animals including body-weight effects, increased relative liver, testes and epididymal weights and hepatocyte hypertrophy was observed at the next highest dose of 194 mg/kg bw/day. At a parental dose of 64 mg/kg bw/day, delays in pinna unfolding were observed in the second litter of the initial parental generation. Delays in pinna unfolding and other developmental landmarks (auditory canal opening, eye opening) were observed in all high dose (194 mg/kg bw/day) litters from both generations. At the high dose level (194 mg/kg bw/day), rarely observed findings of cleft palate (one pup) and anasarca (two pups in two litters) were observed. At a higher dose level (270 mg/kg bw/day) in the one-generation study, additional effects included increased litter loss and decreased pups/dam, live birth index, birth weights and viability index.

Available prenatal developmental toxicity studies consisted of rat and rabbit studies. In rats, developmental toxicity was observed in the presence of significant maternal toxicity. Effects included various visceral variants (dilated renal pelvis, dilated ureter), skeletal variants (incomplete ossification of the basisphenoid, the lumber arch, unossified sternebrae and notched manubrium) and malformations (fused sacral centrum/arch, disconnected cartilage of the sacral arch). In the developmental toxicity study in rabbits, cleft palate, open eye malformations, septal defects, missing lumbar vertebrae and postimplantation loss (embryo-foetal loss) were observed at 120 mg/kg bw/day and in the absence of maternal toxicity. Malformations (open eye, anasarca) and postimplantation loss were also noted at a higher dose level in the rabbit developmental range-finding study in the presence of maternal toxicity.
Anasarca was observed in four fetuses (in one litter) in a range-finding developmental toxicity in rabbits and in one pup in the developmental toxicity study in rats. One incidence of cleft palate was also observed in the rabbit developmental toxicity study. The historical incidences of these findings indicate that they are rare and the relevance of these rare observations in the database at

high dose levels is of concern. Anasarca and cleft palate have also been observed in studies investigating the prenatal toxicity of other morpholine fungicides, including fenprophimorph (anasarca in rats, cleft palate in both rats and rabbits) and tridemorph (cleft palate in rodent[s]).[6] The presence of other developmental effects (vertebral anomalies in rats and rabbits and eye malformations in rabbits) contribute to the concern for potential in utero effects.

The toxicology profile of dodemorph-acetate is summarized in Appendix III.

***Pest Control Products Act* Hazard Characterization**

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account the completeness of the data with respect to the exposure of and toxicity to infants and children and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the database for dodemorph-acetate as it pertains to the toxicity to infants and children, the database is complete. The current database addressing risk to the young following dodemorph-acetate exposure includes a supplemental one-generation reproductive toxicity study, a two-generation reproductive toxicity study, a developmental toxicity study in rats and a developmental toxicity study in rabbits. Data from the reproductive toxicity assay in rats and the developmental toxicity study in rabbits suggest an increased sensitivity of the young.

In the multigenerational reproductive toxicity assay, delays in pinna unfolding were observed in the offspring at the lowest dose of 64 mg/kg bw/day in the absence of maternal toxicity. Other developmental delays (auditory canal opening, eye opening) were observed at 194 mg/kg bw/day and in the presence of maternal toxicity (decreased body weight and body-weight gains). Reduced viability of the young was observed at this dose level as well as a single occurrence of cleft palate and two occurrences of anasarca in two different litters. At a parentally-toxic dose of 270 mg/kg bw/day in the one generation reproductive toxicity study, administration of dodemorph-acetate resulted in litter loss and a decreased number of pups/dam, live birth index, viability index and reduced growth of the young.

In the developmental toxicity study in rabbits, an increase in postimplantation loss (embryo-foetal death) and malformations (including open eye, cleft palate, septal defects and missing lumber vertebrae) were observed at the high dose of 120 mg/kg bw/day (no observed adverse effect level [NOAEL]: 40 mg/kg bw/day). Maternal toxicity was not observed in this study, up to the highest dose tested of 120 mg/kg bw/day. In the range-finding study in rabbits, significant postimplantation loss was noted at a maternally toxic dose level of 200 mg/kg bw/day along with seven fetuses with open eye malformations and four fetuses with anasarca.

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[6] Reffstrup, T.K. and Ostergaard, G. 2001. European Chemicals Bureau: Evaluation of the reproductive toxicity of fenpropimorph and proposal for classification. http://ecb.jrc.it/classlab/7195a99_DK_fenpropimorph.doc.

In the rat developmental toxicity study, variations were noted at a maternally toxic dose of 100 mg/kg bw/day in the form of dilated renal pelvis and dilated ureter. At 300 mg/kg bw/day, an increase in skeletal effects was observed (incomplete ossification of the basisphenoid, lumbar arch and sternebrae and notched manubrium). Malformations at this level included fused sacral centrum/arch, cartilage of the sacral arch not being connected and a single incidence of anasarca.

The literature suggests that some other morpholine fungicides also demonstrate potential teratogenicity. Fenprophimorph has been associated with anasarca in rats and cleft palate in rats and rabbits; tridemorph has been associated with cleft palate in rodents. The malformations and increase in postimplantation loss observed with dodemorph-acetate are considered serious responses. Furthermore, these responses in the rabbit occur at dose levels that do not demonstrate any maternal toxicity. The sensitivity of the fetus coupled with the seriousness of the effect indicates a high level of concern for prenatal toxicity.

3.2 Occupational and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects. However, MOEs less than the target MOE require measures to mitigate (reduce) risk.

3.2.1 Toxicology Endpoint Selection for Occupational and Non-Occupational Risk Assessment

Short- and Intermediate-Term Dermal and Inhalation Risk Assessment
Neither an acceptable repeat-dose dermal nor a repeat-dose inhalation study was available.

For the occupational short- and intermediate-term dermal and inhalation risk assessments, an oral NOAEL of 40 mg/kg bw/day was selected on the basis of increases in postimplantation loss and malformations (open eye, cleft palate, septal defects, missing lumbar vertebrae) observed at the lowest observed adverse effect level (LOAEL) of 120 mg/kg bw/day in a rabbit developmental toxicity study. These endpoints are considered relevant to both the dermal and inhalation risk assessment.

Standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) are applied. As the worker population could include pregnant and lactating women, it is necessary to ensure adequate protection of the fetus or the nursing infant who may be exposed via their mother. In light of concerns regarding prenatal and postnatal toxicity (as outlined in the *Pest Control Products Act* section), an additional 10-fold uncertainty factor was applied to these endpoints. Thus, the target margin of exposure is 1000. This MOE is considered to be protective of all adults as well as nursing infants and the unborn children of exposed women.

Long-Term Dermal and Inhalation Risk Assessment
Neither an acceptable repeat-dose dermal nor a repeat-dose inhalation study was available. For the occupational long-term dermal and inhalation risk assessment, an oral LOAEL of 10 mg/kg bw/day was selected from the one-year dog study, at which dose vomiting and decreased body-weight gains were observed. A NOAEL was not established.

Standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) and an additional 3-fold uncertainty factor to account for the lack of an established NOAEL have been applied. The target MOE is 300. This MOE is considered to be protective of all adults as well as nursing infants and the unborn children of exposed women.

Dermal Absorption
A dermal absorption value of 54% was chosen for the re-evaluation of dodemorph-acetate based on a rat in vivo dermal absorption study submitted to the PMRA. Several limitations were identified in the study, including low recovery and low duration of exposure time. Given the limitations, the dermal absorption factor was calculated by adding the unrecovered dose to the total absorbed dose, with the assumption that the entire unrecovered dose was absorbed. There is a high level of uncertainty in this value as it was based on limited study data.

The toxicology endpoints used in the risk assessment of dodemorph-acetate are summarized in Appendix IV.

3.2.2 Occupational Exposure and Risk Assessment

Workers can be exposed to dodemorph-acetate through mixing, loading or applying the pesticide, and when entering a treated site to conduct activities such as harvesting and/or handling of treated roses.

Mixer, Loader and Applicator Exposure and Risk Assessment
There are potential exposures to mixers, loaders and applicators. The following supported uses were assessed:

- Mixing/loading emulsifiable concentrates
- Groundboom application to field roses
- Mixing/loading/applying by backpack to field and greenhouse roses
- Mixing/loading/applying by high and low pressure handwand to field and greenhouse roses

Based on the typical use pattern, workers applying dodemorph-acetate in the field would generally have a short-term (up to 30 days) duration of exposure while workers applying in the greenhouse would have intermediate- (up to six months) to long-term (more than six months) duration of exposure.

The PMRA estimated handler exposure based on the following level of personal protection as specified on the label.

Baseline Personal Protective Equipment (PPE): Long pants, long sleeved shirts and chemical-resistant gloves (unless specified otherwise). For groundboom application, this scenario does not include gloves, as the data quality was better for non-gloved scenarios than gloved scenarios.

Respirator: Respirator with a National Institute for Occupational Safety and Health (NIOSH)/Mine Safety and Health Administration (MSHA)/British Health and Safety Executive (BHSE) approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a National Institute for Occupational Safety and Health/Mine Safety and Health Administration/British Health and Safety Executive approved canister approved for pesticides.

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment may be refined with exposure data representative of modern application equipment and engineering controls. Biological monitoring data could also further refine the assessment.

No acceptable chemical-specific handler exposure data were submitted for dodemorph-acetate; therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE. In most cases, the PHED did not contain appropriate data sets to estimate exposure to workers wearing a respirator. These values were estimated by incorporating a 90% protection factor for a respirator into the inhalation unit exposure data.

Occupational exposure estimates associated with mixing, loading and applying dodemorph-acetate meet the target MOEs, provided that baseline PPE and respirator (as specified on label) are worn. Therefore, risk to workers handling dodemorph-acetate is not of concern. Refer to Table 1 of Appendix V for more details.

Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers entering treated rose fields and greenhouses. Based on the typical use pattern, there is potential for short-term (< 30 days) postapplication exposure to dodemorph-acetate for workers entering treated fields and intermediate- (up to six months) to long-term exposure (greater than six months) for workers entering treated greenhouses.

Postapplication Dermal Exposure

Default dislodgeable foliar residue (DFR) data and activity-specific transfer coefficients (TCs) were used to estimate postapplication dermal exposure resulting from contact with treated foliage at various times after application. DFR data include the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant, to the skin of the worker. A TC is a factor that relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (e.g. hand harvesting apples, scouting late season corn) and reflect standard agricultural work clothing worn by adult workers. Postapplication exposure activities include harvesting, pinching, pruning, thinning, irrigation, scouting and weeding.

For workers entering a treated site, restricted entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter a treated site. An REI is the duration of time that must elapse before residues decline to a level where the performance of a specific activity results in exposures above the target MOE (i.e. > 1000 for short- to intermediate-term exposure scenarios and >300 for long-term exposure for dodemorph-acetate as described in section 3.2.1).

Two greenhouse DFR studies were available to the PMRA. Both studies were considered to be unacceptable for use in the postapplication assessment due to major limitations identified in each study. As adequate chemical specific data was not available, the default value of 20% of the application rate was used to estimate the peak DFR (day 0 after application) in greenhouse and field roses. For subsequent days after application, the outdoor dissipation rate of 10%/day was used to calculate the DFR on field roses. However, due to differences in application technology and environmental conditions (humidity, temperature, rainfall, ultraviolet light, etc.), the outdoor dissipation rate is not considered to be appropriate for use in estimating DFR dissipation in greenhouses. As there is no default dissipation rate for greenhouses, only day 0 postapplication exposure could be assessed for greenhouse rose workers. In addition, postapplication exposure was calculated assuming one application, although multiple applications are specified on the labels.

For field roses, the exposure estimates for postapplication workers on day 0 of application following only one application were well below the target MOEs and the calculated REIs were not considered to be agronomically feasible (24–31 days). The calculated MOEs ranged from 42 to 84 on day 0 of application, whereas the target MOE was 1000 (Table 2, Appendix V).

For greenhouse roses, the exposure estimates for postapplication workers on day 0 of application following only one application were well below the target MOEs and the REIs could not be calculated due to data limitations (dissipation rate). For short- to intermediate-term exposure, the calculated MOEs ranged from 42 to 84 on day 0 of application, whereas the target MOE was 1000 (Table 2, Appendix V). For long-term exposure, the calculated MOEs ranged from 11 to 21 on day 0 of application, whereas the target MOE was 300 (Table 2, Appendix V).

Thus, based on current data, the risk to postapplication workers is of concern. It must be noted that the exposure assessment for postapplication workers was based on a single application, whereas multiple applications are permitted on the label. A multiple application scenario was not examined as the exposure and risk estimates to postapplication workers from a single application

were already considered to be well below the target MOEs. In addition, risk estimates were calculated using both the high and low rates. Target MOEs were not obtained, even at the lowest rate.

Additional data, as outlined below, could be submitted to address uncertainties in the risk assessment:

- Adequate DFR data for greenhouse and field roses
- Additional dermal absorption data to further refine the dermal absorption factor
- Additional information on the dodemorph-acetate use pattern, including typical rates, number of applications per season, typical work durations
- Data supporting the feasibility of additional protective clothing and/or other mitigation measures suggested by industry for postapplication worker activities

With these additional data and information, it is expected that estimated exposure and risk would be more reflective of actual exposure.

Postapplication Inhalation Exposure
Outdoor (field roses)

An indoor postapplication exposure assessment was not required as dodemorph-acetate meets the North American Free Trade Agreement (NAFTA) criteria for an outdoor inhalation waiver (vapour pressure (VP) $< 1 \times 10^{-4}$ kPa).

Indoor (greenhouse roses)

An indoor (greenhouse) inhalation postapplication exposure assessment was not conducted as adequate data were not available to assess the air concentration of dodemorph-acetate after application. Furthermore, postapplication exposure estimates from the dermal route alone were already considered to be well below the target MOEs.

Additional data, as outlined below, are required in order to conduct the indoor postapplication inhalation exposure assessment:

- Air concentration data in greenhouses following application with relevant equipment

Note that postapplication exposure from the inhalation route is expected to be minimal as the VP of dodemorph-acetate (1.2×10^{-5} kPa) is just above the NAFTA criteria for an indoor inhalation waiver (VP $< 1 \times 10^{-5}$ kPa).

3.2.3 Non-Occupational Exposure and Risk Assessment

Non-occupational risk assessment involves estimating risks to the general population, including children, during or after pesticide application.

As there are no registered residential uses of dodemorph-acetate, exposure and risk to people in and around residential areas is expected to be negligible. Therefore, a non-occupational exposure and risk assessment is not required.

3.3 Dietary Risk Assessment

As dodemorph-acetate is not registered for use on food commodities, the dietary risk assessment considered potential exposure from drinking water sources only.

3.3.1 Toxicology Endpoint Selection for Dietary Exposure and Risk Assessment

The toxicology endpoints used in the risk assessment of dodemorph-acetate are summarized in Appendix IV.

Acute Reference Dose (ARfD) for Females Aged 13–49

To estimate dietary risk from acute (1-day) exposures to dodemorph-acetate, an oral NOAEL of 40 mg/kg bw/day was selected on the basis of increases in postimplantation loss and malformations (open eye, cleft palate, septal defects, missing lumbar vertebrae) observed at the LOAEL of 120 mg/kg bw/day in a rabbit developmental toxicity study (section 3.1). These endpoints could occur following exposure to a single dose and, as such, are considered relevant for use in establishing an acute reference dose.

Standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) were applied. In consideration of the seriousness of the endpoint selected (postimplantation loss and malformations) and it being observed in the absence of maternal toxicity (i.e. sensitivity of the fetus), the *Pest Control Products Act* factor of 10-fold has been retained. The composite assessment factor (CAF) (combined uncertainty factors and *Pest Control Products Act* factor) is 1000.

$$\text{ARfD (Females aged 13–49)} = \frac{40 \text{ mg/kg bw}}{1000} = 0.04 \text{ mg/kg bw}$$

Acute Reference Dose (ARfD) for the General Population (Excluding Females Aged 13–49)

To estimate dietary risk from acute (1-day) exposures to dodemorph-acetate, an oral NOAEL of 40 mg/kg bw was selected on the basis of postdosing salivation and vomiting observed at higher doses in the 28-day gavage and 90-day dietary dog studies (section 3.1). Postdosing vomiting and salivation have been observed in all dog studies (all using different methods of oral exposure) and have been observed following a single exposure in the 28-day gavage and 90-day dietary studies (LOAEL: 80 mg/kg bw/day). The superficial erosion of the gastric mucosa

observed in the one-year dog study and the corrosive properties demonstrated in dermal assays suggest that these effects may be secondary to irritation and not due solely to the species' propensity for vomiting (section 3.1).

Standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) have been applied. In consideration of the completeness of the database, and the use of a more protective acute reference dose for females aged 13–49, the *Pest Control Products Act* has been reduced from 10-fold to 1-fold. This is also considered protective of any postnatal toxicity. The CAF is 100.

$$\text{ARfD (general population)} = \frac{40 \text{ mg/kg bw}}{100} = 0.4 \text{ mg/kg bw}$$

3.3.2 Determination of Acceptable Daily Intake (ADI)

To estimate dietary risk from repeat exposures to dodemorph-acetate, an oral LOAEL of 10 mg/kg bw/day was selected from the 1-year dog study in which dose vomiting and decreased body-weight gains were observed (section 3.1). A NOAEL was not established.

Standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) and an additional 3-fold factor to account for the lack of an established NOAEL have been applied. In consideration of the completeness of the database and the established LOAEL being protective of prenatal and postnatal effects, the *Pest Control Products Act* factor has been reduced from 10-fold to onefold. The CAF is 300.

$$\text{ADI} = \frac{10 \text{ mg/kg bw/day}}{300} = 0.03 \text{ mg/kg bw/day}$$

This reference dose provides a margin of 700 to the NOAEL for delays in pup development (pinna unfolding), 1333 to the lowest NOAEL for malformations, 1333 to the lowest NOAEL for postimplantation loss and 2433 to the NOAEL for ovarian adenocarcinomas identified in the database.

The choice of this endpoint provides an acceptable margin to other endpoints of concern and is considered protective of pregnant females, the unborn child and children.

3.3.3 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) of dodemorph-acetate in potential drinking water sources (groundwater and surface water) were estimated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of dodemorph-acetate in groundwater were calculated using the Leaching Estimation and Chemistry Model (LEACHM) to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using LEACHM are estimates of the flux, or movement, of pesticide into shallow groundwater (2 m or 5 m depth) with time. EECs of dodemorph-acetate in

surface water were calculated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in two types of vulnerable drinking water sources: a small reservoir and a dugout.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Table 3.3 lists the application information used in the model along with EECs in different water sources.

Table 3.3 Level 1 EECs for Potential Sources of Drinking Water

Use Pattern	Groundwater EEC (µg a.i./L)		Surface Water EEC (µg a.i./L)			
			Reservoir		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]
2 × 1.92 kg a.i./ha, at a 3-day interval	0	0	52	20	135	111

1 90th percentile of daily average concentrations.
2 90th percentile of yearly average concentrations.
3 90th percentile of yearly peak concentrations. Highest EEC used for acute dietary exposure assessment.
4 90th percentile of yearly average concentrations. Highers EEC used for chronic dietary exposure assessment.

3.3.4 Drinking Water Exposure and Risk Assessment

Dodemorph-acetate acute and chronic water exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–1996 and 1998 data are based on the reported consumption of more than 20 000 individuals over two non-consecutive survey days. For chronic exposure assessment, consumption data are averaged for the entire United States population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994–1996 and 1998 CSFII consumption data, which took into account dietary patterns and survey respondents, the PMRA concluded that it is most appropriate to report risk for the following population subgroups: the general United States population, all infants (<1 year old), children 1–2, children 3–5, children 6–12, youths 13–19, adults 20–49, females 13–49 and adults 50+ years old. The highest daily and yearly surface water values modelled were used in estimate residue concentrations in water in the acute and chronic dietary assessments, respectively. In a deterministic assessment, the residue estimate for each food commodity (i.e. water for dodemorph-acetate) is expressed as a single value. The exposure estimate is based on the high end residue estimate combined with water consumption data. The chronic dietary risk is calculated by using the average daily consumption of different foods, and

average residue values on those foods, over a 70-year lifetime. This expected intake of residues is compared with the ADI, which is the dose that an individual could be exposed to over a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

As described in its Science Policy Notice SPN2003-01, *Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern*, the PMRA calculates acute dietary risk using food consumption and food residue values. In a deterministic assessment, the risk estimate for each crop is expressed as a single value. For dodemorph-acetate, the exposure estimate is based on the high-end water residue estimate combined with water consumption data. An exposure value representing the high end (95^{th} percentile) of this distribution is compared with the ARfD, which is the dose to which an individual could be exposed on any given day and expect no adverse health effects. When the calculated intake, called the potential daily intake, from residues is less than the ARfD, the intake is not considered to be of concern.

Dodemorph-acetate exposure estimates from drinking water were below 100% of the ARfD and ADI for all population groups and not considered to be of concern. Refer to Appendix VI for details.

3.4 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources from all known or plausible exposure routes (oral, dermal and inhalation).

As dodemorph-acetate is not registered for use in residential areas and food commodities, exposure and risk from residential/non-occupational and food commodities are expected to be negligible. Therefore, an aggregate risk assessment is not required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Dodemorph-acetate is a soluble chemical in water under acidic or neutral conditions (Table 1 of Appendix VII). Its solubility diminishes markedly under alkaline conditions. The log K_{ow} of dodemorph-acetate indicates that there is a potential for bioaccumulation under alkaline conditions. Overall, dodemorph-acetate is a not a persistent substance in soil and water. Phototransformation is rapid in both media and is the dominant mode of transformation in soils, except under acidic conditions. The soil phototransformation dissipation time to 50% (DT_{50}) is 2.7 days. Although there were no studies of phototransformation on plant surfaces, it is a major route of transformation in soils and, therefore, phototransformation is expected to be the dominant mode of transformation on vegetation. Biotransformation is also an important mode of transformation in soil. It is also the dominant mode of transformation in the water column and sediment. In the water column, dodemorph-acetate is not persistent (DT_{50} in water is 17 hours). However, in sediment it persists longer (DT_{50} is 21–750 days). There are no data available on

anaerobic biotransformation in water-sediment systems. However, based on the data in anaerobic soils, it is presumed that dodemorph-acetate is very stable under these conditions. Dodemorph-acetate is not a mobile chemical in soils and, therefore, is unlikely to leach to groundwater. This is because it occurs as a cation under acid and neutral conditions and is subject to electrostatic adsorption. Sorption coefficient values (organic carbon partition coefficient; K_{oc}) in studies with different soil textures ranged from 4200 to 48 000. The vapour pressure of dodemorph-acetate indicates that it has potentially intermediate to high volatility under field conditions. Volatilization of dodemorph-acetate may be an important route of dissipation in the environment. The volatilization rate is 2.9% of the applied active ingredient in 24 hours. Therefore, within seven days, about 20% can be volatilized.

No terrestrial or aquatic field dissipation studies or bioconcentration studies were available for dodemorph-acetate.

4.2 Effects on Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. EECs are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity); the RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Effects on Terrestrial Organisms

The lowest LD_{50} for the honeybee is 88.5 µg a.i./bee based on 48 hour oral exposure (Table 2, Appendix VII). For the earthworm the only LC_{50} (14 d study) value available is >1000 mg a.i./kg dry soil (Table 2, Appendix VII). The lowest NOEC for the earthworm is 500 mg product/kg dry soil (Table 2, Appendix VII). For beneficial arthropods the most sensitive species is the parasitoid *Aphidius rhopalosiphi* with a 48 hour LD_{50} of 248.8 g a.i./ha (Table 2, Appendix VII). Studies of dodemorph-acetate toxicity to birds (in Germany) were carried out with Mehitaumittel, a formulated end-use product. Studies with the technical grade active ingredient are not available. The most sensitive species is the Japanese quail with an acute oral LD_{50} of 1284 mg a.i./kg bw (Table 2, Appendix VII). There were no reproductive data for birds. For mammals, the acute oral LD_{50} for the rat was 4500 mg a.i./kg bw (Table 2, Appendix VII). Mammals show reproductive sensitivity to dodemorph-acetate (Table 5, Appendix VII). The most sensitive NOEL was 21 mg a.i./kg bw for the rat (Table 2, Appendix VII).

Dodemorph-acetate was not found to be a risk to bees or earthworms at any of the application regimes (Tables 6 and 9, Appendix VII). However, the risk quotients did exceed the LOC for beneficial arthropods (Table 7, Appendix VII). Non-target spray drift of dodemorph-acetate also exceeded the LOC for beneficial arthropods (Table 8, Appendix VII).

The risk was assessed for the different feeding guilds (insectivore, granivore, frugivore and herbivore) and sizes (small, medium and large) of birds and mammals from the consumption of food sprayed directly with dodemorph-acetate (Tables 3–5, Appendix VII). For birds, the risk exceeded the LOC for small- and medium-sized insectivores and for large herbivores (Table 3, Appendix VII). It also exceeded the LOC for frugivores and granivorous birds at higher application frequencies (Table 3, Appendix VII). An assessment was conducted to determine the risk to birds from non-target spray drift (American Society of Agricultural Engineers (ASAE) fine droplet size). Birds were not found to be at risk from consuming food sources contaminated with spray drift (Table 3, Appendix VII). No data were available on the dietary or reproductive toxicity of dodemorph-acetate to birds.

For mammals, dodemorph-acetate applications to food sources exceeded the acute LOC for medium- and large sized herbivores but not for the other feeding guilds (Table 4, Appendix VII). For herbivorous mammals, the risk from non-target spray drift (ASAE fine droplet size) was found to be less than the LOC (Table 4, Appendix VII). The reproductive risk assessment indicated that the risk quotients for all of the different sizes and feeding guilds of mammals exceeded the LOC. The reproductive risk from spray drift exceeded the LOC for medium- and large-sized herbivorous mammals (Table 5, Appendix VII).

The risk assessment results are based on the assumption that 100% of the diet of birds and mammals is contaminated with dodemorph-acetate. However, given the mobile nature of these animals it is likely that food sources contaminated with dodemorph-acetate would at most comprise only a small fraction of the diet. Moreover, roses are not generally part of the diet of birds and most mammals and use of this product is not extensive in any one area. Therefore, it is unlikely that exposure to dodemorph-acetate would present a significant risk to birds and mammals.

4.2.2 Effects on Aquatic Organisms

For freshwater invertebrates, the lowest 48-hour EC_{50} was 1.8 for *Daphnia magna* (Table 2, Appendix VII). A 21-day study of the life cycle toxicity of *Daphnia magna* indicated a NOEC of 0.45 mg a.i./L (Table 2, Appendix VII). For freshwater fish the only data available was for the rainbow trout. The 96-hour LC_{50} was 3.04 mg a.i./L (Table 2, Appendix VII). No toxicological data were available for warm water species of fish or the early life stage of freshwater fish. For amphibians, the rainbow trout acute 96-hour LC_{50} (above) was used as a surrogate in the risk assessment. For freshwater green algae, the lowest EC_{50} (72 hour test) was 5.15 mg a.i./L with the species *Pseudokirchneriella subcapitata* based on biomass (Table 2, Appendix VII). The NOEC for this species was 2.66 mg a.i./L (Table 2, Appendix VII).

The risk quotients for the acute risk to fish, the acute and chronic risks to invertebrates and the acute risk to algae from dodemorph-acetate use exceeded the LOC at the screening level (Tables 10, 12, 14 and 18, Appendix VII). However, refined exposure estimates show the risk from contamination by spray drift to water bodies did not exceed the LOCs for fish, aquatic invertebrates or algae (Tables 11, 13, 15 and 19, Appendix VII). A refined risk assessment was also carried out to determine the risk to fish, aquatic invertebrates and algae from dodemorph-acetate in runoff (Tables 20, 21 and 22 and 24, Appendix VII). The risks were found to be less than the LOCs.

Dodemorph-acetate was found to exceed the LOC for amphibians at the screening level (Table 16, Appendix VII). A refined risk assessment was carried out to determine the risk to amphibians from dodemorph-acetate in runoff. The risk quotients were less than the LOC (Table 23, Appendix VII). For spray drift to water, the risk to amphibians exceeded the LOC at the higher use rates and frequencies (Table 17, Appendix VII). Therefore, aquatic buffer zones will be required to protect amphibians from dodemorph-acetate use.

No toxicological data were available on potential effects on aquatic macrophytes or estuarine/marine fish and invertebrates; therefore, the risks could not be determined. However, based on the limited use pattern, additional data are not required at present, but may be required if there is a use expansion in the future.

5.0 Value

5.1 Commercial Class Products

Appendix I lists all dodemorph-acetate products that are registered in Canada as of August, 2008. Appendix II lists all the uses for which dodemorph-acetate is presently registered; the registrant continues to support these uses.

5.1.1 Commercial Class Alternatives to Dodemorph-acetate

The registered chemical alternatives for the uses of dodemorph-acetate that the registrant continues to support but that have risk concerns are listed in Appendix VIII. The PMRA has not commented on the availability and extent of use of these alternatives.

Most non-chemical alternatives are usually focused on sanitation, quarantine and general cultural practices, including removal of infested plant materials (including weeds), avoiding irrigation late in the day, use of tolerant varieties and selection of healthy plant materials for propagation. The effectiveness and extent of use of these non-chemical pest management practices have not been verified. The PMRA welcomes feedback on the availability and extent of use of the chemical alternatives to dodemorph-acetate listed in Appendix VIII and further information regarding the availability, effectiveness and extent of use of non-chemical pest management practices for any of the registered uses of dodemorph-acetate. This information will allow the PMRA to refine sustainable pest management options for the listed site-pest combinations.

5.2 Value of Dodemorph-Acetate

Dodemorph-acetate is used to control powdery mildew on greenhouse- and field-grown roses. In Canada, it is estimated that a total of about 153 ha of roses are grown (greenhouse: 23 ha and outdoor: 130 ha). It is important for the management of powdery mildew resistance on roses by providing an alternate mode of action to fungicides from other chemical families. Dodemorph-acetate is of economic value to the field-grown and particularly to the greenhouse-grown rose industry, where it is an efficient and economical method of controlling powdery mildew. Use of dodemorph-acetate is most critical for greenhouse roses, which are grown all year long, given there is low tolerance of disease on this high value crop. Dodemorph-acetate is also an integral part of integrated powdery mildew management programs for greenhouse- and field-grown roses in Canada.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, dodemorph-acetate was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of dodemorph-acetate were also considered, including transformation products formed in the environment and contaminants and formulants in the technical product and the end-use product. Dodemorph-acetate and its transformation products were evaluated against the following Track 1

criteria: persistence in soil ≥182 days; persistence in water ≥182 days; persistence in sediment >365 days; persistence in air ≥2 days; bioaccumulation log K_{ow} ≥5 or bioconcentration factor (BCF) ≥5000 (or bioaccumulation factor (BAF) ≥5000). In order for dodemorph-acetate or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use product, including formulants, were assessed against the contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern.* The PMRA has reached the following conclusions.

- Dodemorph-acetate does not meet Track 1 criteria. Dodemorph-acetate does not meet the Track 1 criterion for persistence, as its half-life values in water (4–17 hours), soil (29–73 days) and sediment (117–221 days) are below the Track 1 criteria. Although volatilization is an important route of dissipation (vapour pressure 9.2 x 10^{-5} mm of mercury), dodemorph-acetate does not meet the Track 1 criterion for persistence in air because its phototransformation half-life is quite short (less than three days).
- Dodemorph-acetate does not meet the Track 1 criterion for bioaccumulation, as its octanol–water partition coefficient (log K_{ow} 2.5–4.2, section 2.2) is below the Track 1 criterion. Therefore, dodemorph-acetate does not meet the Track 1 criteria and is not considered a Track 1 substance.
- Dodemorph-acetate does not form any transformation products that meet the Track 1 criteria.
- There are no Track 1 formulants in the technical product or end-use product.
- There are no Track 1 contaminants in the technical product or end-use product.

6.1 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical and end-use products are assessed against the formulants and contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.* This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations including: the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montréal Protocol); and the PMRA Formulants Policy as described in the PMRA Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* is maintained and used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* consists of three parts:

- Part 1: Formulants of Health or Environmental Concern;
- Part 2: Formulants of Health or Environmental Concern that are Allergens Known to cause Anaphylactic-Type Reactions; and
- Part 3: Contaminants of Health or Environmental Concern.

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances and are considered in section 6.1. The following assessment refers to the formulants and contaminants in Part 1 and Part 2 of the list.

Technical grade dodemorph-acetate and the end-use product Meltatox do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

7.0 International Context

Dodemorph-acetate is no longer registered in the United States. The conditional registration was cancelled in July 1993.

Recently, the European Food Safety Authority (EFSA) issued its conclusion regarding its peer-review of a dodemorph-acetate risk assessment and accepted its use as a fungicide on roses.

8.0 Incident Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set timeframe. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, from minor effects such as skin rashes, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and take appropriate measures when there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable. These measures will range from minor label changes to discontinuation of the product.

As of 3 July 2008, there were no incident reports submitted for dodemorph-acetate.

9.0 Summary

9.1 Human Health and Safety

The toxicology database submitted for dodemorph-acetate is adequate to define the majority of toxic effects that may result from exposure to it. Dodemorph-acetate was not genotoxic or carcinogenic to mice or male rats. A slight increase in rare ovarian adenocarcinomas was observed in female rats exposed to high doses of dodemorph-acetate for two years. The target organ of dodemorph-acetate is the liver, with effects including increases in liver weights and various histopathological findings of the liver being observed at doses at or above doses causing body-weight effects and/or vomiting in test animals. When dodemorph-acetate was given to pregnant rats, a shortened gestation period was observed in the dams, with delays in pup development also being observed. Increases in prenatal mortality (including embryo-foetal death) as well as malformations of the fetus have also been observed following exposure of the pregnant animal to dodemorph-acetate.

9.1.1 Occupational Risk

Risk estimates associated with mixing, loading and applying dodemorph-acetate are not of concern, provided personal protective equipment is worn according to label directions. Postapplication risks to workers are of concern:

- For field roses, the exposure estimates for postapplication workers were well below the target MOE on day 0 of application and the calculated REIs were not considered to be agronomically feasible (24–31 days). The exposure estimates were based on postapplication exposure after only one application.

- For greenhouse roses, the exposure estimates for postapplication workers were well below the target MOE on day 0 of application and the REIs could not be calculated due to insufficient data. The exposure estimates were based on postapplication exposure after only one application.

9.1.2 Dietary Risk from Food and Drinking Water

As dodemorph-acetate is not registered for use on food commodities, the dietary risk assessment considered potential exposure from drinking water sources only (section 9.1.3).

9.1.3 Dietary Risk from Drinking Water

Risk estimates for potential exposure from drinking water are not of concern. Dietary exposure from drinking water was less than 100% of the ARfD and ADI for the general population and all other population subgroups.

9.1.4 Residential Risk

A residential risk assessment was not required as dodemorph-acetate is not registered for use in residential areas.

9.1.5 Aggregate Risk

An aggregate risk assessment was not required as dodemorph-acetate is not registered for use in residential areas or on food commodities.

9.2 Environmental Risk

The use of dodemorph-acetate on roses does not present a significant risk to aquatic organisms, except for amphibians from spray drift. The risk to amphibians can be mitigated through the use of buffer zones. Additional risk-reduction measures are recommended. Given the limited extent to which it is used outdoors in Canada (130 ha), dodemorph-acetate is not expected to present a significant risk to birds, mammals, bees or earthworms.

9.3 Value

Dodemorph-acetate is registered to control powdery mildew on greenhouse- and field-grown roses. It is an integral part of integrated powdery mildew management on roses and also an important tool for resistance management. The PMRA welcomes feedback on the availability and extent of use of the chemical alternatives to dodemorph-acetate listed in Appendix VIII and further information regarding the availability, effectiveness and extent of use of non-chemical pest management practices for control of powdery mildew in roses. This information will allow the PMRA to refine sustainable pest management options for this use in the future.

10.0 Proposed Regulatory Decision

After a re-evaluation of the fungicide dodemorph-acetate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing to phase out the sale and use of dodemorph-acetate products in Canada.

An evaluation of available scientific information found that, under the current conditions of use, the human health risks estimated for dodemorph-acetate do not meet current standards. In particular, there are risk concerns for postapplication workers in greenhouse and field rose production that cannot be sufficiently mitigated based on current information. In order to address some of the uncertainties in the occupational risk assessment, it is possible that additional data and use information could be submitted. The PMRA also welcomes information on the value of dodemorph-acetate and of alternative control methods. Any relevant information provided during the proposed re-evaluation decision consultation period will be considered prior to a final decision.

10.1 Proposed Regulatory Action Related to Human Health

Based on an evaluation of available scientific information, the human health risks estimated for dodemorph-acetate, under the current conditions of use, do not meet current standards and a phase out of dodemorph-acetate products is proposed. No additional statements on end-use product labels are being proposed at this time to protect workers; however, following the proposed re-evaluation decision consultation period, additional measures could be recommended if appropriate.

For the technical product, dodemorph-acetate was found to be extremely irritating to the skin, severely irritating to the eyes and is a potential skin sensitizer. Therefore, the following warning statement should appear on the label of the technical product: "Poison, Danger: Skin Irritant and Corrosive to the Eyes, Potential Skin Sensitizer."

10.2 Proposed Regulatory Action Related to Environment

Pending the outcome of this re-evaluation, initial label statements to address environmental risk are included in this document (see Appendix IX).

10.3 Proposed Regulatory Action Related to Value

There are no regulatory actions related to value proposed at this time.

11.0 Additional Data Requirements

11.1 Data Requirements Related to Occupational Exposure Assessment

Additional data could be submitted to address uncertainties in the postapplication occupational exposure and risk assessment. As the estimated MOEs for postapplication workers on day 0 of application were well below target MOEs (greater then 10× smaller; see Table 2 of Appendix V), a highly refined data set would need to be submitted in order to possibly reduce exposure estimates and increase MOEs to acceptable levels (i.e. passive dosimetry/biomonitoring studies).

DACO 5.2 Use information for postapplication activities, including:

- data on typical rate and number of applications per season;
- data supporting the feasibility of additional protective clothing and/or other mitigation measures that could be suggested by industry for post application worker activities;
- data to support rates of application lower than the registered rates; and
- data that supports typical work durations that are lower than 8 hours

DACO 5.6 /5.7 Postapplication: Passive Dosimetry/Biomonitoring.

DACO 5.8	In vivo Dermal Absorption—as the dermal absorption value used in this assessment was based on limited study data and represents an uncertainty in the risk assessment, additional dermal absorption data for dodemorph-acetate could help to refine the dermal absorption factor.
DACO 5.9	Dislodgeable Foliage Residue (for both greenhouse roses and field roses following application with relevant equipment)–as data from available DFR studies could not be used quantitatively because of major limitations identified in each study.
DACO 5.10	Ambient Air Samples—additional data is required to determine dodemorph-acetate air concentrations in greenhouses after application.

List of Abbreviations

μg	microgram
μm	micrometer
1/n	exponent for the Freundlich isotherm
AB	Alberta
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
BAF	Bioaccumulation Factor
BC	British Columbia
BCF	Bioconcentration Factor
BHSE	British Health and Safety Executive
bw	body weight
CAF	composite assessment factor
CAS	Chemical Abstracts Service
cm	centimetre(s)
CSFII	Continuing Survey of Food Intakes by Individuals
DEEM-FCID™	Dietary Exposure Evaluation Model Software with the Food Commodity Intake Database
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DT_{50}	dissipation time to 50% (the time required to observe a 50% decline in concentration)
DT_{75}	dissipation time to 75% (the time required to observe a 75% decline in concentration)
DT_{90}	dissipation time to 90% (the time required to observe a 90% decline in concentration)
dw	dry weight
DWLOC	drinking water level of comparison
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
EFSA	European Food Safety Authority
EXAMS	Exposure Analysis Modeling System
FC	food consumption
FIR	food ingestion rate
g	gram(s)
ha	hectare(s)
Hg	mercury
HPLC	high performance liquid chromatography
IRED	Interim Reregistration Eligibility Decision (USEPA Document)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%

LD_{50}	lethal dose to 50%
LEACHM	Leaching Estimation and Chemistry Model
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
LOQ	limit of quantitation
MB	Manitoba
mg	milligram(s)
mL	millilitre
mm	millimetre(s)
MOE	margin of exposure
MS	mass spectrometry
MSHA	Mine Safety and Health Administration
N/A	not applicable
NAFTA	North America Free Trade Agreement
NB	New Brunswick
NIOSH	National Institute for Occupational Safety and Health
NL	Newfoundland and Labrador
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NS	Nova Scotia
OC	organic carbon content
OM	organic matter content
ON	Ontario
PChE	plasma cholinesterase
PE	Prince Edward Island
PHED	Pesticide Handlers Exposure Database
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM/EXAMS	Pesticide Root Zone Model/Exposure Analysis Modeling System
QC	Québec
REI	restricted entry interval
SBI	sterol biosynthesis inhibitors
SK	Saskatchewan
$t_{½}$	half-life
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
URMULE	User Requested Minor Use Label Expansion
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VP	vapour pressure
v/v	volume per volume dilution

Appendix I Registered Dodemorph-Acetate Products as of 20 August 2008 from the PMRA Electronic Label Collection

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
19334	Technical	BASF Canada Inc.	BASF Technical dodemorph-acetate	Solid	96%
11798	Commercial	BASF Canada Inc.	BASF Meltatox Powdery Mildew Fungicide	Emulsifiable Concentrate or Emulsion	384 g/L

Appendix II Registered Commercial Class Uses of Dodemorph-Acetate in Canada as of 20 August 2008 from the PMRA Electronic Label Collection

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate		Maximum Number of Applications per Year[3]	Typical Number of Days Between Applications	Supported Use[4]
				Maximum Single[1]	Maximum Cumulative[2]			
Greenhouse-grown roses, excluding the variety Tropicana (Superstar) and certain cultivars of Tropicana such as "Command Performance"	Powdery mildew	Emulsifiable Concentrate or Emulsion	Ground application equipment	0.96 g a.i./L of water = 0.96 to 1.92 kg a.i./ha	24 kg a.i./ha	25	10–14	Y
Field-grown roses, excluding the variety Tropicana (Superstar) and certain cultivars of Tropicana such as "Command Performance"	Powdery mildew	Emulsifiable Concentrate or Emulsion	Ground application equipment	0.96 g a.i./L of water = 0.96 to 1.92 kg a.i./ha	24 kg a.i./ha	25	10–14	Y

1 The registrant advised that this product is applied to roses in 1000–2000 L water/ha.

2 Maximum cumulative rate calculated based on rate of 0.96 kg/ha x 25 applications/year.

3 The registrant advised that a maximum of 25 applications could be made per year.

4 Y = use supported by the registrant.

Appendix III Toxicology Profile for Dodemorph-Acetate

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise specified.

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
Metabolism/Toxicokinetic Studies			
ADME, Oral (gavage) Rat, Wistar 3–4/sex/group PMRA#1210592 (2003)	Purity: 94.0% Acute: 10 or 1000 mg/kg bw Repeat: 10 mg/kg bw/day for 14 days ^{14}C-Dodemorph delivered on 14th day of repeat Vehicle: corn oil		Absorption: Peak absorption occurs rapidly (six hours following dosing) although at a substantially slower rate at the high dose. 10 mg/kg bw: T_{max} @ 6 hours C_{max} ♂>♀ (♂:1.6 mg/kg plasma, ♀:1.2 mg/kg plasma) 1000 mg/kg bw: T_{max} @ 48 hours C_{max} ♂=♀ (♂:73 mg/kg plasma, ♀:76 mg/kg plasma) Distribution: Residual tissue activity is low, with the greatest organ accumulation in the liver (<0.8%) and, to lesser degrees, the kidney, bone, adrenals and fat. Concentrations in the carcass and blood are similar, with higher concentrations (three to fourfold) identified in the abdominal fat, suggesting the possibility for sequestration into fat stores. However, concentrations in all tissues were similar following a repeat dose regimen, suggesting a low probability for bioaccumulation. Metabolism: The parent compound was not identified in the urine, but small amounts were identified in the feces (not quantified). The metabolite profile appeared similar for both urine and feces. The metabolites were predominantly polar, but were unable to be characterized. Supplemental: metabolites not characterized
			Excretion: Following low dose exposure (acute or repeat), urinary excretion accounted for 36–39% of radiolabel excreted by males and 28–31% by females. Total urinary excretion was decreased slightly following exposure to the high dose. At the low dose, urinary excretion was rapid at low doses following acute (♂/♀:93%/90% @ 24 hours) and repeat dose (♂/♀:89%/86% @ 24 hours) exposures, whereas following acute exposure to the high dose, urinary excretion occurred primarily between 24 and 48 hours (♂/♀:73%/71% from 24 to 72 hours). Excretion through volatiles occurred in a similar timeframe observed in urinary metabolism (for both high and low dose groups), accounting for 7–13% of total radiolabel. As with urinary excretion, a slight increase in excretion through volatiles was observed in all male

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
		dose groups relative to female groups. Radiolabel excreted in the feces accounted for 45–50% of radiolabel in the males and 61–66% of dose in the females with no major differences in total radiolabel by test group. Excretion via feces occurred primarily within the first 24 hours for the low dose groups and between 24 and 72 hours for the high dose group. Radiolabel identified in feces was consistently higher in the female groups compared to male groups.	
Acute Toxicity Studies			
Acute Toxicity, Oral, Gavage Rat, Sprague-Dawley 10/sex/group (1970)	1600, 3200, 4000, 5000 or 6400 mg/kg bw	LD_{50} = 4500 mg/kg bw ≥1600 mg/kg bw: slight ataxia (♀ more sensitive). ≥3200 mg/kg bw: dyspnoea, restlessness, slight ataxia (recovery in surviving animals between day 4 and 6). Serosanguineous incrustation of nostril, diarrhea and feces on anal area in intercurrent mortalities. Chronic bronchitis and bronchiectasis in sacrificed animals. Low toxicity	
Acute Toxicity, Oral, Gavage Rat, Sprague-Dawley 5/sex/group (1992)	Purity: 98.2% 4200, 4600 or 5000 mg/kg bw	LD_{50} > 5000 mg/kg bw ≥4200 mg/kg bw: tachypnea, lethargy, catalepsy, nostril discharge, hemorrhaging of the stomach and small intestine, discoloration of the liver, thymus and kidneys. Low toxicity	
Acute Toxicity, Oral (gavage) Rabbit, Russian 2 animals/group (6♂, 4♀) (1970)	1000, 2000, 2500, 3000 or 4000 mg/kg bw)	LD_{50} = 2000 mg/kg bw ≥1000 mg/kg bw: transient anorexia, diarrhea, slight weight loss. ≥2000 mg/kg bw: anorexia, mortality (one animal at 4 hours 4000 mg/kg bw: atony, ataxia, mortality (20–48 hours) Intercurrent mortalities: odour of compound in stomach (two), reddening of gastric mucosa (two), foci of necrosis in liver Low toxicity	
Acute Toxicity, Dermal Rabbit, NZW 5/sex/group PMRA#1025246	Purity: 98.2% 2000 mg/kg bw	LD_{50} > 2000 mg/kg bw 2000 mg/kg bw: necrosis of the skin at application site Low toxicity	

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
(1992)			
Acute Toxicity, Inhalation PMRA#1210568 (2003)		Requirement waived for the following reasons: Chemical found to be corrosive to rabbit skin. Dodemorph-acetate was unable to be prepared at a suitable aerosolization. Considered of High Toxicity due to waiver and irritative properties.	
Dermal Irritation, Rabbit, NZW 1 animal PMRA#1210568 (2002)	Purity: 98.2% 0.5 mL, 4 hours	24 hours: Severe edema after patch removal, not apparent on day 7 Moderate to severe erythema, well-defined on day 7 2 days: Dark necrotic area, well defined on day 7 Extremely irritating to the skin	
Eye Irritation, Rabbit Rabbit, NZW 3 animals (1988)	Purity: 99.6% 0.1 mL, 24 hours Monitored 21 day	Severe corneal opacity all time periods (3/3) Severe conjunctivitis all time periods (3/3) Iritis (3/3) Severely irritating to the eyes	
Dermal Sensitization, (Maximization Test) Guinea Pig, Albino 5 ♀ control, 10 ♀ test group PMRA#1210571 (2001)	Purity: 94.0% Day 1: 1:1 FCA/water, 1% dodemorph-acetate and 2% mixture (1:1 FCA/ dodemorph-acetate) Day 7: Induction with 0.5 mL 20% dodemorph-acetate Day 21: Challenge 5% dodemorph-acetate with corn oil (0.15 mL each)	Grade 1 to 2 skin reactions with 24–48 hours following challenge. Eschar formation in the skin of one animal @ 48 hours Positive for skin sensitization Potential Skin Sensitizer	
Subchronic Toxicity Studies			
90-Day Toxicity Oral, Feeding	Purity: 98.2%	79/94	≥94 mg/kg bw/day: ↓bwg (-7.5%) (♀) *(not considered adverse)*

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
Rats, Sprague-Dawley 10/sex/group PMRA#1210577 (2003)	0, 200, 1200 or 3600 ppm (♂/♀: 0, 20/23, 79/94 or 299/259 mg/kg bw/day)		299/259 mg/kg bw/day: ↓ fc, ↓ bw, ↓ bwg, ↓ glucose, ↑ relative liver weight; aggressive, agitated, nervous behaviours (♂); centrilobular hypertrophy (liver) (♀) No effects on ophthalmology, hematology, urinalysis, gross pathology or behavioural Fecal Occult Blood (FOB) tests.
28-Day Toxicity, Oral, Gavage Dog, Beagle 3/sex/group PMRA#1210575 (1977)	Purity: 100% 0, 40, 80 or 160 mg/kg bw/day vehicle: methylhydroxy-ethylcellulose gel		≥80 mg/kg bw/day: postdosing vomiting and salivation (6/6, beginning on day 1); hepatic fatty degeneration (2/3) (♀) 160 mg/kg bw/day: postdosing sedation, decreased appetite, pultaceous feces, ↓ bw, ↓ bwg, ↓ fc, ↑ absolute liver weight, ↑ relative liver weight; ↓ absolute brain weight, hepatic congestion (1/3) (♀) There were no treatment-related effects on hematology, clinical chemistry, urinalysis, ophthalmology, a simple noise test or an electrocardiogram. Supplemental: low animal numbers, poor study reporting
90-Day Toxicity, Oral, Dietary Dog, Beagle 3/sex/group PMRA#1210576 (1977)	0, 1000, 2500 or 6250 ppm (0, 32/32, 79/79, 187/193 mg/kg bw/day)		≥32 mg/kg bw/day: ↓ fc (♂); degenerative changes of the liver (♀) ≥79 mg/kg bw/day: postdosing salivation and vomiting (>day 1), ↑ relative kidney, ↑ relative liver, fatty degeneration of the liver; ↓ bw, ↓ bwg, ↑ absolute liver weight, degenerative changes of the liver (♂); pale livers, postdosing sedation (♀) ≥184 mg/kg bw/day: ↓appetite, ↑ alt, ↑ alk; sedation, ↑ relative lung weight, pale livers, cirrhosis (1/3) (♂); ↓ bw (15%) ↓ bwg, slight ↓ fc (-4.7%), ↑ absolute liver weight, pulmonary inflammation consistent with aspiration pneumonia (♀) There were no treatment-related effects on hematology, urinalysis, ophthalmology, a simple noise test or an electrocardiogram. Supplemental: low animal numbers, poor study reporting

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
52-Week Toxicity, Oral, Capsule Dog, Beagle 4/sex/group PMRA#1210577, 1210578 (2003)	Purity: 98.2% 0, 10, 25 or 62.5 mg/kg bw/day	LOAEL: 10	≥10 mg/kg bw/day: vomiting (>week 17); ↓ bwg (-33%) (♂) ≥25 mg/kg bw/day: abnormal feces, ↑ salivation, liver: bile duct hyperplasia, ↑ lipofuscin, peribiliary fibrosis; ↑ alt (♂); ↓ bwg, liver: vacuolar degeneration stomach erosion (superficial, pyloric region) with inflammation, ↑ alk (week 13) (♀) 63.5 mg/kg bw/day: ↑ alk, ↑ ggt, liver: ↑ pigmentation,↑ macrophages; ↓ fc, ↑ relative liver weight, liver: granulated/nodular surface with peribiliary and perilobular fibrosis, vacuolar degeneration, stomach erosion (superficial, pyloric region) with inflammation, epididymal vacuolation, one animal terminated in moribund state (♂); ↑ alt (♀) There were no effects on ophthalmology, electrocardiogram, hematology or urinalysis.
Chronic Toxicity/Oncogenicity Studies			
Carcinogenicity, Oral, Dietary Mouse, CD-1 50/sex/group PMRA#1448461 (2004)	Purity: 98.2% 0, 300, 1000 or 3000 ppm (♂/♀: 0, 45/55, 152/184 or 455/545 mg/kg bw/day) 18 months	45/55	≥152/184 mg/kg bw/day: ↓ bw, bwg; ↑ relative testes weight, ↑ relative liver weight (♂) 455/545 mg/kg bw/day: ↓ fc, ↑ relative liver weight, eosinophilic foci (liver); ↑ absolute liver weight, ↑ lymphoid cell infiltration of the epididyides (♂) There were no treatment-related effects on clinical symptoms, hematology or gross pathology. No evidence of carcinogenicity.
Chronic/ Carcinogenicity Oral, Dietary Rat, Sprague-Dawley 50/sex/group PMRA #1448462 (2004)	Purity: 98.2% 0, 300, 1000 or 3000 ppm (♂/♀: 0/0, 16/21, 55/73, 166/222 mg/kg bw/day) 24 months	55/73	≥55/73 mg/kg bw/day: ↓ bwg (weeks 1–25) (Not considered adverse) 166/222: ↓ fc (weeks 1–13), peribiliary fibrosis, proliferation biliary duct, eosinophilic foci (liver); ↑ relative testes weight, fatty changes (liver) (♂); ↑ relative liver weight @ 1 year, ↓ relative liver weight, ↑ relative lung with, mineralization (lung), foamy macrophages (lung), centrilobular hypertrophy (liver, @ 1 year), alveolar hyperplasia, ovarian adenocarcinomas (2/50) (♀) Equivocal evidence of carcinogenicity. (Ovarian adenocarcinomas are rare, no preneoplastic

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
			lesions observed) There were no treatment-related effects on clinical signs, mortality, palpable mass examination, opthamology, hematology, clinical chemistry or urinalysis
Reproductive and Developmental Toxicity Studies			
Reproductive Toxicity (One Genenation, Range-Finding) Oral, Dietary Rat, Wistar 10/sex/group PMRA#1210580 (1992)	0, 600, 1200 or 2400 ppm (0, 70, 140, 270 mg/kg bw/day)		Parental ≥70 mg/kg bw/day: ↓ bwg (premating) (♀) ≥140 mg/kg bw/day: ↓ cholesterol, ↑ creatinine (♂); ↓ bw, ↓ bwg (gestation), slight ↓ fc (♀) 270 mg/kg bw/day: ↓ bw, bwg (♂) Reproductive 270 mg/kg bw/day: ↓ birth weight, total litter loss (2 dams), ↓ pups/dam, ↓ live birth index Offspring ≥70 mg/kg bw/day: ↓ bwg (Lactation Day 7–14) ≥140 mg/kg bw/day: ↓ bwg (Lactation Day 7–14) 270 mg/kg bw/day: ↓ viability index Supplemental: study design, poor study reporting
Reproductive Toxicity (Two Generations) Oral, Dietary Rat, Wistar 25/sex/group PMRA#1210583 (1994)	Purity: 92.6% 0, 200, 600 or 1800 ppm (0, 21, 64 or 194 mg/kg bw/day)	Parental: 64 Repro: 21 Offspring: 21	Parental 194 mg/kg bw/day: ↓ bw, ↓ bwg, ↓ fc, ↓ cholesterol; ↑ relative testes weight, ↑ relative epididymides weight (♂); slight ↑ relative liver weight, hypertrophy periacinar hepatocytes (F0, F1) (♀) Reproductive ≥64 mg/kg bw/day: ↓ gestation interval (F0–second mating) 194 mg/kg bw/day: ↓ gestation interval (F0–both matings), ↓ pup birth weight Offspring ≥64 mg/kg bw/day: ↓ bw, ↓ bwg, delayed pinna unfolding (F1b)

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
			194 mg/kg bw/day: delayed pinna unfolding, delayed auditory canal opening, delayed eye opening, ↓ viability, cleft palate (1 pup), anasarca (2 pups, 2 litters) No generational effects observed. Evidence of sensitivity of the young.
Developmental Toxicity Oral, Gavage Rat, Wistar 25♀/group PMRA#1210579 (2001)	Purity: 98.8% 0, 30, 100 or 300 mg/kg bw/day Gestation Days 6–19 Vehicle: olive oil	Maternal: LOAEL 30 Develop: 30	Maternal ≥30 mg/kg bw/day: ↓bwg ≥100 mg/kg bw/day: salivation (transient), ↑ neutrophils, ↓ bilirubin, ↑ triglycerides 300 mg/kg bw/day: ↓ fc, ↑ ggt, ↑ cholesterol, ↑ platelets, ↑ absolute liver weight, ↑ relative liver weight Developmental control: anasarca (1 fetus, 1 litter) 100 mg/kg bw/day: dilated renal pelvis, dilated ureter 300 mg/kg bw/day: ↑ skeletal effects: (incomplete ossification of the basisphenoid, the lumbar arch, fused sacral centrum/arch, unossified sternebrae, the cartilage of the sacral arch not being connected and notched manubrium), anasarca (1 fetus, 1 litter)
Developmental Toxicity Oral, Gavage Rabbit, Himalayan 15♀/group PMRA#1210582 (1994)	Purity: 92.6% 0, 10, 40 or 120 mg/kg bw/day Gestation Days 7–19 Vehicle: olive oil	Maternal: 40 Develop: 40	Maternal 120 mg/kg bw/day: ↓ gravid uterine weight (*considered secondary to postimplantation loss*), postimplantation loss Developmental 120 mg/kg bw/day: post implantation loss, open eye malformations (4 fetuses, 1 litter), cleft palate (1 fetus, 1 litter), septal defects (2 fetuses, 2 litters), missing lumbar vertebrae (2 fetuses, 2 litters). Evidence of sensitivity of the young.
Developmental Toxicity Oral, Gavage	Purity: 92.6% 0, 200, 600 or 900 mg/kg bw/day		Maternal: 200 mg/kg bw/day: ↓ fc, ↓ bw, ↓ bwg, ↑ alt, ↑ ggt, ↑ cholesterol, ↑ postimplantation loss, ↓ placental weight

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
Rabbit, Himalayan 4–5♀/group PMRA#1210581 (1994)	Gestation Day 7–19 Vehicle: olive oil		≥600 mg/kg bw/day: mortality, 100% postimplantation loss Developmental: 200 mg/kg bw/day: ↑ postimplantation loss (57.4%), ↓ bw open eye malformation (7/16 fetuses, 1/3 litters), anasarca (4/16 fetuses, 1/3 litters) Study considered supplemental.
Genotoxicity Studies			
In Vitro			
Ames Mutagenicity, *S. typhimurium* TA98, TA100, TA1535, TA1537 and TA1538 (1985)	0, 0.001, 0.005, 0.01, 0.05, 0.1 µL/late ±S9		Negative
HGPRT locus, Mutagenicity CHO (1986)	Purity: >99% 0, 0.01, 0.0215, 0.0464, 0.1, 0.215, 0.464 mg/mL ±S9		Negative
Chromosomal aberration, CHO (1985)	0, 0.02, 0.04, 0.22, 0.33, 2 µg/mL ±S9		Negative Study considered supplemental.
Unscheduled Deoxyribonucleic acid synthesis (UDS) assay, Rat hepatocyte (1986)	0, 0.5, 1.0, 2.5, 5.0, 10, 15, 20, 30, 50 mg/mL		Negative

Study/Species/ Number of Animals Per Group	Dose Levels/Purity of Test Material	NOAEL (mg/kg bw/day)	Results/Effects
Deoxyribonucleic acid (DNA) repair *E. coli* p3478 (polA-) W3110 (polA+) (1985)	0, 0.005, 0.01, 0.05, 0.1, 0.5 µLmL ±S9	Negative Study considered supplemental.	
In Vivo			
Micronucleus assay, Oral, Gavage Mice, NMRI 5/sex/group (1984)	Purity: >99% 0, 250, 500 or 1000 mg/kg bw vehicle: 0.5% CMC	Negative ≥250 mg/kg bw: piloerection ≥500 mg/kg bw: irregular respiration, excitation 1000 mg/kg bw: apathy, atony, spastic gait, squatting posture	

Appendix IV Toxicology Endpoints for Health Risk Assessment for Dodemorph-Acetate

	RfD Dose (mg/kg bw)	Study NOAEL (or LOAEL)	CAF or Target MOE and Rationale[1]
Acute Reference Dose **Females 13–49**	0.04	NOAEL: 40 mg/kg bw/day Rabbit Developmental Toxicity (postimplantation loss, cleft palate, open eye, septal defects, missing lumbar vertebrae)	1000 *Pest Control Products Act* = 10-fold
Acute Reference Dose **General Population**	0.4	NOAEL: 40 mg/kg bw/day 28-Day Dog, 90-Day Dog Studies (postdosing salivation, vomiting)	100 *Pest Control Products Act* = onefold
Acceptable Daily Intake **General Population**	0.03	LOAEL: 10 mg/kg bw/day 1-Year Dog Study (vomiting, decreased bwg)	300 *Pest Control Products Act* = onefold threefold use of a LOAEL
Short-Term Dermal Intermediate-Term Dermal[2] **Short-Term Inhalation Intermediate-Term Inhalation[3]**		NOAEL: 40 mg/kg bw/day Rabbit Developmental Toxicity (postimplantation loss, cleft palate, open eye, septal defects, missing lumbar vertebrae)	1000 Concern for unborn child = 10-fold
Long-Term Dermal[2] **Long-Term Inhalation[3]**		LOAEL: 10 mg/kg bw/day 1-Year Dog Study (vomiting, decreased bwg)	300 threefold use of a LOAEL

1 CAF refers to the total of uncertainty and *Pest Control Products Act* factors for dietary risk assessments, MOE refers to target MOE for occupational assessments

2 As an oral NOAEL was selected, a dermal absorption factor of 54% is used in a route-to-route extrapolation.

3 As an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) is used in route-to route extrapolation.

Appendix V Occupational Exposure Risk Estimates for Dodemorph-Acetate

Table 1 Mixer/Loader/Applicator Commercial Applicator Exposure and Risk Assessment

Use Site	Application Equipment	Application Rate	Area Treated Per Day (ATPD)	A.I. Handled per day (kg)	Dermal (M/L/A)		Inhalation (M/L/A)		Margin of Exposure[3]		
					Unit Exposure[1] (µg/kg a.i.)	Exposure[2] (µg a.i./kg bw/day)	Unit Exposure[1] (µg/kg a.i.)	Exposure[2] (µg a.i./kg bw/day)	Dermal	Inhalation	Combin
Short- to Intermediate-Term Exposure and Risk									**Target MOE = 1000**		
Greenhouse and Field Roses	Backpack	0.96 g a.i./L	150 L	0.14	5446	6.05	6.21	0.013	6611	3131150	6598
	High Pressure Handwand	0.96 g a.i./L	150 L	0.14	5585	6.2	15.1	0.031	6447	1287712	6415
	Low Pressure Handwand	0.96 g a.i./L	3750 L	3.6	943	26.2	4.52	0.232	1527	172075	1513
	Groundboom[4]	1.92 kg a.i./ha[5]	30 ha	57.6	84	37.38	0.26	0.211	1070	189887	1064
Long-Term Exposure and Risk									**Target MOE = 300**		
Greenhouse Roses	Backpack	0.96 g a.i./L	150 L	0.14	5446	6.05	6.21	0.013	1653	782788	1650
	High Pressure Handwand	0.96 g a.i./L	150 L	0.14	5585	6.2	15.1	0.031	1612	321928	1604
	Low Pressure Handwand	0.96 g a.i./L	3750 L	3.6	943	26.2	4.52	0.232	382	43019	378

Personal Protective Equipment: long sleeved shirt, long pants, chemical resistant gloves (where applicable) and respirator.

ATPD = Area Treated Per Day, MOE = Margin Of Exposure, A.I. = Active Ingredient, M/L/A = Mixer/Loader/Applicator

1 From Pesticide Handlers Exposure (PHED) Database.

2 Exposure (µg/kg/day) = (unit exposure × kg a.i. handled per day × 54% dermal absorption factor (dermal route only))/70 kg bw.

3 MOE for short to intermediate term exposure based on inhalation/oral NOAEL of 40 mg/kg/day based on a rabbit developmental toxicity study, target M
MOE for long-term exposure based on inhalation/oral LOAEL of 10 mg/kg/day from a 1-year dog study, target MOE is 300.

4 Gloves were not included in the groundboom application scenarios as the data quality was better for non-gloved scenarios than gloved scenarios.

5 Rate in kg a.i./ha derived label rate and BASF spray volume information - high end spray volume estimate (2000 L/ha) × label rate (0.96 g/L) = 1920 g/l

Table 2 Dermal Postapplication Exposure and Risk Assessment

Use Site	Re-Entry Activity	Transfer Coefficient[1] (cm^2/hr)	Rate (µg a.i./cm^2)[2]		Peak DFR (µg/cm^2)[3]		Dermal Exposure (µg/kg bw/day)[4]		Day 0 Margin of Exposure[5]		Re-Entry Interval[6]	
			Low	High	Low Rate	High Rate	Low Rate	High Rate	Low Rate	High Rate	Low Rate	Hig Ra
Short to Intermediate Term Exposure									**Target MOE = 1000**			
Field Roses	All activities	4000	9.6	19.2	1.92	3.84	473.97	947.99	84	42	24	31
Greenhouse Roses	All activities	4000	9.6	19.2	1.92	3.84	473.97	947.99	84	42	N/A	N/
Long-term Exposure									**Target MOE = 300**			
Greenhouse Roses	All activities	4000	9.6	19.2	1.92	3.84	473.97	947.99	21	11	N/A	N/

1 application was assumed. A multiple application scenario was not performed as REIs after one application were already not considered to be a

Shaded cells indicate MOEs that are less than the target MOE.

DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = Restricted Entry Interval, N/A = Not Applicable

1 The transfer coefficient was based on the PMRA TC value for cut flowers.

2 Rate derived from label rate and BASF spray volume information - 1000–2000 L/ha × label rate of 0.96 g/L = 9.6 -19.2 µg/cm^2

3 Default peak DFR value of 20% of the rate on day 0.

4 Dermal Exposure = (TC × DFR × 8 hour work day × 54% dermal absorption factor)/70 kg adult body weight.

5 MOE for short to intermediate term exposure based on dermal NOAEL of 40 mg/kg/day from a rabbit developmental toxicity study, ta
MOE for long-term dermal exposure based on LOAEL of 10 mg/kg/day from a 1-year dog toxicity study, target MOE of 300.

6 REI only application for field re-entry workers as there is no default dissipation rate for greenhouse roses. Default dissipation rate of 1

Appendix VI Drinking Water Exposure and Risk Estimates by Population Groups for Dodemorph-Acetate

Table 1 Acute Drinking Water Exposure by Population Subgroups

Population Subgroup	Acute Exposure	
	mg/kg bw/day	% ARfD[1]
General Population[2]	N/A	N/A
All infants (<1 year)	0.027	7
Children 1–2 years	0.011	3
Children 3–5 years	0.010	3
Children 6–12 years	0.007	2
Males 13–19 years	0.006	1
Males 20–49 years	0.006	2
Adults 50+ years	0.006	1
Females 13–49 years	0.007	16

ARfD = Acute Reference Dose.

[1] ARfD = 0.04 mg/kg bw for females ages 13–49, 0.4 mg/kg bw for all other population groups. 95% of exposure.

[2] The risk estimate could not be determined for the general population as separate ARfDs were selected for females aged 13–49 years and the other population groups.

Table 2 Chronic Drinking Water Exposure by Population Subgroups

Population Subgroup	Chronic Exposure	
	mg/kg bw/day	% ADI[1]
General Population	0.002	8
All infants (<1 year)	0.008	27
Children 1–2 years	0.004	12
Children 3–5 years	0.003	11
Children 6–12 years	0.002	8
Youth 13–49 years	0.002	6
Adults 20–49 years	0.002	8
Adults 50+ years	0.002	8
Females 13–49 years	0.002	8

ADI=Acceptable Daily Intake

[1] ADI= 0.03 mg/kg bw/day for all populations.

Appendix VII Environmental Fate and Toxicity of Dodemorph-Acetate

Table 1 Fate and Behaviour in the Environment

Study Type	Test Material	Study Conditions	Value or Endpoint	Interpretation	Major Transformation Products	Reference
Abiotic Transformation						
Hydrolysis	Dodemorph-acetate	pH 5, 7 and 9. 25°C.	Stable at pH 5, 7 and 9	Not a major route of transformation	Not reported	PMRA #1210613
Phototrans-formation –soil	Dodemorph-acetate	Sandy loam. No transformation in dark controls.	DT_{50} 2.7 days	A major route of transformation	Not reported	PMRA #1210612
Phototrans-formation –water		25°C. No transformation in dark controls.	Stable at pH 5. DT_{50} 4 days pH 7 DT_{50} 1.8 days pH 9	A major route of transformation at pH 7 and 9	Not reported	PMRA #1210615
Phototrans-formation –air	Dodemorph-acetate	No data	No data			
Biotransformation						
Soil –aerobic	Dodemorph-acetate	Loamy sand, pH 5.6 OC 0.5% First order degradation	DT_{50} 37.8 DT_{90} 125.4	An important route of transformation	Not reported	PMRA #1210616
	Dodemorph-acetate	Various soil textures. pH not reported. First order degradation	DT_{50} DT_{90} 29.6 days 326 Sandy loam 44.3 days 399 *Cis* isomer 8.4 days 44 *Trans* isomer 27.2 days 230 Silt loam 32.7 days 294 *Cis* isomer 7.2 days 79 *Trans* isomer	An important route of transformation		PMRA #1210617
	Dodemorph-acetate	Sandy Loam. pH 8. 1.7% OM. First order degradation	73. 1 days	An important route of transformation	Not reported	PMRA #1210618
Soil –anaerobic	Dodemorph-acetate	Sandy loam. pH 8. 1.7% OM.	Stable	Persistent. Not an important route of transformation.	Not reported	PMRA #1210618

Study Type	Test Material	Study Conditions	Value or Endpoint	Interpretation	Major Transformation Products	Reference
Water/ sediment –aerobic	Dodemorph-acetate	Two sediment water systems studied designated as OVP (silty clay loam) and SW (silt loam). pH = 8.1 and 7.7. OC = 4.3 and 7.4%. Application rate 1 kg a.i./ha. DT_{50}'s refer to the two systems. 20°C. Degradation water square root first order, sediment linear, total system square root 2nd order. DT_{50} OVP extrapolated.	DT_{50} 3.5–17 hours (DT_{90} 6–8 days) water column 221–117 days sediment 642–31 days total system	An important route of transformation in water. Not an important route of transformation in water; persistent in sediment.	No transformation products in water. Individual transformation products <10% in sediment.	PMRA #1319238
		Two sediment water systems studied designated as SS and OS. pH 7.4 and 7.0. OC = 1.3 and 1.0 %.	DT_{50} 48.5–21 days	An important route of transformation	Not reported	PMRA #1319219
Water/ sediment –anaerobic	Dodemorph-acetate	No data	No data			
Mobility						
Adsorption /desorption	Dodemorph-acetate	Plainfield sand. OM 0.3%	K_{oc} 4200	Low mobility	Not reported	PMRA #1319241
		California sandy loam. OM 0.8–1.7%	K_{oc}5400	Immobile	Not reported	PMRA #1319241
		Kauwanee clay loam. OM 5%	K_{oc} 5300	Immobile	Not reported	PMRA #1319241
		Mississippi silt loam. OM 1.1%	K_{oc} 48000	Immobile	Not reported	PMRA #1319241
		Arizona silty clay loam. OM 1.4%	K_{oc} 41000	Immobile	Not reported	PMRA #1319241
Adsorption /desorption	Dodemorph-acetate	Boden I Loam OC 0.58%	K_{oc} 91.3	Immobile	Not reported	PMRA #1319242
		Boden II Loamy sand. OC 2.66%	K_{oc} 98.1	Immobile	Not reported	PMRA #1319242
		Boden III Sand. OC 0.51%	K_{oc} 42.1	Slight mobility	Not reported	PMRA #1319242

Study Type	Test Material	Study Conditions	Value or Endpoint	Interpretation	Major Transformation Products	Reference
Soil column leaching	Dodemorph-acetate	Canfield sandy loam (2 columns). Application. Rate 1.5 kg a.i./ha. OM 2.8% Columns aged 15 days. 30% AR recovered as bound residue (0–5 cm). 44.5% recovered as dodemorph-acetate (*cis* to *trans* ratio ≈ 3 to 1). Dodemorph-acetate in leachate < 1%. Total extractable in soil column ≈ 54%. Unextractable (bound) residues ≈ 30%. Mass balance 95% of applied.	83% of applied retained in top 5 cm. 1% of applied retained in 5–10 cm layer. No movement below 12 cm.	Immobile	Not reported	PMRA #1319340; 1319243
Soil Volatiliz-ation	Dodemorph-acetate	20°C. Airspeed 1 m/s. Recovery 70–110%. pH 5.7. Sand 6.5%, silt 25.3%, clay 68.2%. Soil moisture 9% at start and 6% and end of experiment (50% of holding capacity).	2.94% volatilized in 24 hours.	An important route of dissipation	Not reported	PMRA #1319245; 1319244
Field Studies						
Field dissipation	Dodemorph-acetate	No data	No data			

Table 2 Toxicity to Non-Target Species

Organism	Study Type	Species	Test Material	Endpoint*	Value (Effect)	Effect Of Concern	Reference Number
Terrestrial Species							
Invertebrate	Acute oral	Honeybee (*Apis mellifera*)	Dodemorph-acetate	48 hours LD_{50}	>138.8 µg a.i./bee	Mortality	PMRA #1319307
		Honeybee	Dodemorph-acetate	48 hours LD_{50}	88.5 µg a.i./bee	Mortality	PMRA #1326156
	Acute contact	Honeybee (*Apis mellifera*)	Dodemorph-acetate	48 hours LD_{50}	>100.0 µg a.i./bee	Mortality	PMRA #1319307
		Honeybee	Dodemorph-acetate		179.6 µg a.i./bee	Mortality	PMRA #1326156
		Parasitoid *Aphidius rhopalosiphi*	Dodemorph-acetate	48 hours LD_{50}	248.8 g a.i./ha	Mortality	PMRA #1326158
		Predatory mite *Typhlodromus pyri*	Dodemorph-acetate	7 days LD_{50}	353 g a.i./ha.	Mortality	PMRA #1326157
	Acute contact	Earthworm (*Eisenia foetida*)	Dodemorph-acetate	14 days LC_{50} NOEC	>1000 mg a.i./kg dry soil 500 mg product/kg dry soil	Mortality	PMRA #1319305
Birds	Acute oral	Japanese Quail (*Coturnix japonica*)	Mehitaumittel formulated end use product	LD_{50}	1284 mg a.i./kg bw	Mortality	PMRA #1326162
		Mallard (*Anas platyrhynchos*)		LD_{50}	>4000 mg a.i./kg	Mortality	
	Dietary	None available		None available			
	Reproduc-tion	None available		None available			
Mammals	Acute oral	Rat	Dodemorph-acetate	LD_{50}	4500 mg a.i./kg bw	Mortality	PMRA #1210562
	Dietary	None available		None available			
	Reproduc-tion	Rat	Dodemorph-acetate	NOEL	21 mg a.i./kg bw	Reproduction	PMRA #1210583
		Rabbit	Dodemorph-acetate	NOEL	40 mg a.i./kg bw	Reproduction	PMRA #1210582
Aquatic Species							
Invertebrates	Acute	*Daphnia magna*	Dodemorph-acetate	48 hours EC_{50}	1.8 mg a.i./L	Immobility	PMRA #1319309
		Daphnia magna	Dodemorph-acetate	48 hours EC_{50}	5.4 mg a.i./L		PMRA #1326159

Organism	Study Type	Species	Test Material	Endpoint*	Value (Effect)	Effect Of Concern	Reference Number
	Chronic	*Daphnia magna*	Dodemorph-acetate	21 days LC_{50} 21 days NOEC	0.59 mg a.i./L 0.45 mg a.i./L	Immobility	PMRA #1582584
Fish	Acute	Rainbow trout (*Oncorhynchus mykiss*)	Dodemorph-acetate	96 hours LC_{50}	3.04 mg a.i./L	Mortality	PMRA #1326160
	Chronic (Early Life Stage)	None available		None available			
Algae	Acute	Green alga (*Pseudokirchneriella subcapitata*)	Dodemorph-acetate	72 hours EC_{50} 72 hours NOEC	8.6 mg a.i./L 2.66 mg a.i./L	Growth rate	PMRA #1326163
			Dodemorph-acetate	96 hours EC_{50} 96 hours NOEC	12.7 mg a.i./L 2.66 mg a.i./L	Growth rate	PMRA #1326163
		Green alga (*Pseudokirchneriella subcapitata*)	Dodemorph-acetate	72 hours EC_{50} 72 hours NOEC	5.15 mg a.i./L 2.66 mg a.i./L	Biomass	PMRA #1326163
Algae	Acute	Green alga (*Pseudokirchneriella subcapitata*)	Dodemorph-acetate	96 hours EC_{50} 96 hours NOEC	4.95 mg a.i./L 2.66 mg a.i./L	Biomass	PMRA #1326163
Vascular Plants	Acute	None available	Dodemorph-acetate	None available			

Table 3 Risk Assessment for Terrestrial Organisms (I): Screening Level Acute Risk to Birds from Consumption of Dodemorph-Acetate in Contaminated Food

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute Risk Quotient In-Field	In-Field LOC Exceeded	Acute Risk Quotient Off-Site (6% Spray Drift)	Off-Site LOC Exceeded
20	5.1	Insectivore	0.96 × 2	1.748	49	85.65	0.67	No	Negligible risk	—
			1.92 × 2	3.495		171.26	1.33	Yes	0.08	No
			0.96 × 3	2.617		128.23	0.99	No	Negligible risk	—
			1.92 × 3	4.797		235.05	1.83	Yes	0.11	No
			0.96 × 5	4.277		209.57	1.63	Yes	0.09	No
			1.92 × 5	8.555		419.20	3.26	Yes	0.19	No
			0.96 × 11	7.986		391.31	3.05	Yes	0.18	No
			1.92 × 11	15.971		782.58	6.09	Yes	0.36	No
		Granivore	0.96 × 2	1.748	13	22.72	0.18	No	Negligible risk	—
			1.92 × 2	3.495		45.43	0.35	No	Negligible risk	—
			0.96 × 3	2.617		34.02	0.26	No	Negligible risk	—
			1.92 × 3	4.797		62.36	0.48	No	Negligible risk	—
			0.96 × 5	4.277		55.60	0.43	No	Negligible risk	—
			1.92 × 5	8.555		111.22	0.86	No	Negligible risk	—
			0.96 × 11	7.986		103.82	0.80	No	Negligible risk	—
			1.92 × 11	15.971		207.62	1.62	Yes	0.10	No
20	5.1	Frugivore	0.96 × 2	1.748	25	43.7	0.34	No	Negligible risk	—
			1.92 × 2	3.495		87.37	0.68	No	Negligible risk	—
			0.96 × 3	2.617		65.43	0.51	No	Negligible risk	—
			1.92 × 3	4.797		119..93	0.93	No	Negligible risk	—
			0.96 × 5	4.277		106.93	0.83	No	Negligible risk	—
			1.92 × 5	8.555		213.87	1.67	Yes	0.10	No

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute Risk Quotient In-Field	In-Field LOC Exceeded	Acute Risk Quotient Off-Site (6% Spray Drift)	Off-Site LOC Exceeded
			0.96 × 11	7.986		199.65	1.55	Yes	0.09	No
			1.92 × 11	15.971		399.28	3.10	Yes	0.19	No
100	19.9	Insectivore	0.96 × 2	1.748	38	66.42	0.52	No	Negligible risk	—
			1.92 × 2	3.495		132.81	1.03	Yes	0.06	No
			0.96 × 3	2.617		99.45	0.77	No	Negligible risk	—
			1.92 × 3	4.797		182.29	1.42	Yes	0.08	No
			0.96 × 5	4.277		162.53	1.27	Yes	0.08	No
			1.92 × 5	8.555		325.09	2.53	Yes	0.15	No
			0.96 × 11	7.986		303.47	2.36	Yes	0.14	No
			1.92 × 11	15.971		606.90	4.73	Yes	0.28	No
100	19.9	Granivore	0.96 × 2	1.748	9.9	17.30	0.13	No	Negligible risk	—
			1.92 × 2	3.495		34.60	0.27	No	Negligible risk	—
			0.96 × 3	2.617		25.91	0.20	No	Negligible risk	—
			1.92 × 3	4.797		47.49	0.37	No	Negligible risk	—
			0.96 × 5	4.277		42.34	0.33	No	Negligible risk	—
			1.92 × 5	8.555		84.69	0.66	No	Negligible risk	—
			0.96 × 11	7.986		79.06	0.62	No	Negligible risk	—
			1.92 × 11	15.971		158.11	1.23	Yes	0.07	—
		Fructivore	0.96 × 2	1.748	20	34.96	0.27	No	Negligible risk	—
			1.92 × 2	3.495		69.90	0.54	No	Negligible risk	—
			0.96 × 3	2.617		52.34	0.41	No	Negligible risk	—
			1.92 × 3	4.797		95.94	0.75	No	Negligible risk	—
			0.96 × 5	4.277		85.54	0.67	No	Negligible risk	—
			1.92 × 5	8.555		171.10	1.33	Yes	0.08	No

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute Risk Quotient In-Field	In-Field LOC Exceeded	Acute Risk Quotient Off-Site (6% Spray Drift)	Off-Site LOC Exceeded
			0.96 × 11	7.986		159.72	1.24	Yes	0.07	No
			1.92 × 11	15.971		319.42	2.49	Yes	0.15	No
		Insectivore	0.96 × 2	1.748	2.9	5.07	0.04	No	Negligible risk	—
			1.92 × 2	3.495		10.13	0.08	No	Negligible risk	—
			0.96 × 3	2.617		7.59	0.06	No	Negligible risk	—
			1.92 × 3	4.797		13.91	0.10	No	Negligible risk	—
			0.96 × 5	4.277		12.40	0.10	No	Negligible risk	—
			1.92 × 5	8.555		24.81	0.19	No	Negligible risk	—
			0.96 × 11	7.986		23.16	0.18	No	Negligible risk	—
			1.92 × 11	15.971		46.32	0.36	No	Negligible risk	—
1000	58.1	Granivore	0.96 × 2	1.748	2.9	5.07	0.04	No	Negligible risk	—
			1.92 × 2	3.495		10.13	0.08	No	Negligible risk	—
			0.96 × 3	2.617		7.59	0.06	No	Negligible risk	—
			1.92 × 3	4.797		13.91	0.11	No	Negligible risk	—
			0.96 × 5	4.277		12.40	0.10	No	Negligible risk	—
			1.92 × 5	8.555		24.81	0.19	No	Negligible risk	—
			0.96 × 11	7.986		23.16	0.18	No	Negligible risk	—
			1.92 × 11	15.971		46.32	0.36	No	Negligible risk	—
1000	58.1	Fructivore	0.96 × 2	1.748	5.8	10.13	0.08	No	Negligible risk	—
			1.92 × 2	3.495		20.27	0.16	No	Negligible risk	—
			0.96 × 3	2.617		15.18	0.12	No	Negligible risk	—

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute Risk Quotient In-Field	In-Field LOC Exceeded	Acute Risk Quotient Off-Site (6% Spray Drift)	Off-Site LOC Exceeded
			1.92 × 3	4.797		27.83	0.22	No	Negligible risk	—
			0.96 × 5	4.277		24.81	0.19	No	Negligible risk	—
			1.92 × 5	8.555		49.62	0.39	No	Negligible risk	—
			0.96 × 11	7.986		46.31	0.36	No	Negligible risk	—
			1.92 × 11	15.971		92.63	0.72	No	Negligible risk	—
		Herbivore	0.96 × 2	1.748	114	199.27	1.55	Yes	0.09	No
			1.92 × 2	3.495		398.43	3.10	Yes	0.19	No
			0.96 × 3	2.617		298.33	2.32	Yes	0.14	No
			1.92 × 3	4.797		546.86	4.26	Yes	0.26	No
			0.96 × 5	4.277		487.58	3.79	Yes	0.23	No
			1.92 × 5	8.555		975.27	7.59	Yes	0.46	No
			0.96 × 11	7.986		910.40	7.09	Yes	0.42	No
			1.92 × 11	15.971		1820.69	14.18	Yes	0.85	No
1000	58.1	Herbivore	0.96 × 2	1.748	114	199.27	1.55	Yes	0.09	No
			1.92 × 2	3.495		398.43	3.10	Yes	0.19	No
			0.96 × 3	2.617		298.33	2.32	Yes	0.14	No
			1.92 × 3	4.797		546.86	4.26	Yes	0.26	No
			0.96 × 5	4.277		487.58	3.79	Yes	0.23	No
			1.92 × 5	8.555		975.27	7.59	Yes	0.46	No
			0.96 × 11	7.986		910.40	7.09	Yes	0.42	No
			1.92 × 11	15.971		1820.69	14.18	Yes	0.85	No

AR = Application Rate kg a.i./ha.
CAR = Cumulative Application Rate taking into consideration the foliar half-life (kg a.i./ha).
FF = Feeding Factor = proportion body weight consumed per day × EEC nomogram
EEC nomogram value from PMRA Guidance Manual.
EDE = FF × CAR.
Off-Site RQ = FF × (CAR × 6%)
NR = Negligible Risk Spray (off-site) drift risk assessment is not required).

Table 4 Risk Assessment for Terrestrial Organisms (I): Screening Level Acute Risk to Mammals from Consumption of Dodemorph-Acetate in Contaminated Food

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site (6% Spray drift)	Off-Site LOC Exceeded
15	2.2	Insectivore	0.96 × 2	1.748	28	48.9	0.11	No	Negligible risk	—
			1.92 × 2	3.495		97.9	0.22	No	Negligible risk	—
			0.96 × 3	2.617		73.3	0.16	No	Negligible risk	—
			1.92 × 3	4.797		134.3	0.30	No	Negligible risk	—
			0.96 × 5	4.277		119.8	0.27	No	Negligible risk	—
			1.92 × 5	8.555		239.5	0.53	No	Negligible risk	—
			0.96 × 11	7.986		223.6	0.50	No	Negligible risk	—
			1.92 × 11	15.971		447.2	0.99	No	Negligible risk	—
		Granivore	0.96 × 2	1.748	7.3	12.8	0.03	No	Negligible risk	—
			1.92 × 2	3.495		25.5	0.06	No	Negligible risk	—
			0.96 × 3	2.617		19.1	0.04	No	Negligible risk	—
			1.92 × 3	4.797		35.0	0.08	No	Negligible risk	—
			0.96 × 5	4.277		31.2	0.07	No	Negligible risk	—
			1.92 × 5	8.555		62.5	0.14	No	Negligible risk	—
			0.96 × 11	7.986		58.3	0.13	No	Negligible risk	—
			1.92 × 11	15.971		116.6	0.26	No	Negligible risk	—
15	2.2	Frugivore	0.96 × 2	1.748	15	26.2	0.06	No	Negligible risk	—
			1.92 × 2	3.495		52.4	0.12	No	Negligible risk	—
			0.96 × 3	2.617		39.3	0.09	No	Negligible risk	—

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site (6% Spray drift)	Off-Site LOC Exceeded
			1.92 × 3	4.797		72.0	0.16	No	Negligible risk	—
			0.96 × 5	4.277		64.2	0.14	No	Negligible risk	—
			1.92 × 5	8.555		128.3	0.29	No	Negligible risk	—
			0.96 × 11	7.986		119.8	0.27	No	Negligible risk	—
			1.92 × 11	15.971		239.6	0.53	No	Negligible risk	—
35	4.5	Insectivore	0.96 × 2	1.748	25	43.7	0.10	No	Negligible risk	—
			1.92 × 2	3.495		87.4	0.19	No	Negligible risk	—
			0.96 × 3	2.617		65.4	0.15	No	Negligible risk	—
			1.92 × 3	4.797		119.9	0.27	No	Negligible risk	—
			0.96 × 5	4.277		106.9	0.24	No	Negligible risk	—
			1.92 × 5	8.555		213.9	0.48	No	Negligible risk	—
			0.96 × 11	7.986		199.7	0.44	No	Negligible risk	—
			1.92 × 11	15.971		399.3	0.89	No	Negligible risk	—
35	4.5	Granivore	0.96 × 2	1.748	6.4	11.2	0.02	No	Negligible risk	—
			1.92 × 2	3.495		22.4	0.05	No	Negligible risk	—
			0.96 × 3	2.617		16.7	0.04	No	Negligible risk	—
			1.92 × 3	4.797		30.7	0.07	No	Negligible risk	—
			0.96 × 5	4.277		27.4	0.06	No	Negligible risk	—
			1.92 × 5	8.555		54.8	0.12	No	Negligible risk	—
			0.96 × 11	7.986		51.1	0.11	No	Negligible risk	—
			1.92 × 11	15.971		102.2	0.23	No	Negligible risk	—

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site (6% Spray drift)	Off-Site LOC Exceeded
		Frugivore	0.96 × 2	1.748	13	22.7	0.05	No	Negligible risk	—
			1.92 × 2	3.495		45.4	0.10	No	Negligible risk	—
			0.96 × 3	2.617		34.0	0.08	No	Negligible risk	—
			1.92 × 3	4.797		62.4	0.14	No	Negligible risk	—
			0.96 × 5	4.277		55.6	0.12	No	Negligible risk	—
			1.92 × 5	8.555		111.2	0.25	No	Negligible risk	—
			0.96 × 11	7.986		103.8	0.23	No	Negligible risk	—
			1.92 × 11	15.971		207.6	0.46	No	Negligible risk	—
35	4.5	Herbivore	0.96 × 2	1.748	311	543.6	1.21	Yes	0.07	No
			1.92 × 2	3.495		1086.9	2.42	Yes	0.14	No
			0.96 × 3	2.617		813.9	1.81	Yes	0.11	No
			1.92 × 3	4.797		1491.9	3.32	Yes	0.20	No
			0.96 × 5	4.277		1330.1	2.96	Yes	0.18	No
			1.92 × 5	8.555		2660.6	5.91	Yes	0.35	No
			0.96 × 11	7.986		2483.6	5.52	Yes	0.33	No
			1.92 × 11	15.971		4967.0	11.04	Yes	0.66	No
1000	68.7	Insectivore	0.96 × 2	1.748	3.2	5.6	0.01	No	Negligible risk	—
			1.92 × 2	3.495		11.2	0.02	No	Negligible risk	—
			0.96 × 3	2.617		8.4	0.02	No	Negligible risk	—
			1.92 × 3	4.797		15.4	0.03	No	Negligible risk	—
			0.96 × 5	4.277		13.7	0.03	No	Negligible risk	—
			1.92 × 5	8.555		27.4	0.06	No	Negligible risk	—
			0.96 × 11	7.986		25.6	0.06	No	Negligible risk	—
			1.92 × 11	15.971		51.1	0.11	No	Negligible risk	—

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site (6% Spray drift)	Off-Site LOC Exceeded
1000	68.7	Granivore	0.96 × 2	1.748	3.4	5.9	0.01	No	Negligible risk	—
			1.92 × 2	3.495		11.9	0.03	No	Negligible risk	—
			0.96 × 3	2.617		8.9	0.02	No	Negligible risk	—
			1.92 × 3	4.797		16.3	0.04	No	Negligible risk	—
			0.96 × 5	4.277		14.5	0.03	No	Negligible risk	—
			1.92 × 5	8.555		29.1	0.06	No	Negligible risk	—
			0.96 × 11	7.986		27.2	0.06	No	Negligible risk	—
			1.92 × 11	15.971		54.3	0.12	No	Negligible risk	—
		Frugivore	0.96 × 2	1.748	6.8	11.9	0.03	No	Negligible risk	—
			1.92 × 2	3.495		23.8	0.05	No	Negligible risk	—
			0.96 × 3	2.617		17.8	0.04	No	Negligible risk	—
			1.92 × 3	4.797		32.6	0.07	No	Negligible risk	—
			0.96 × 5	4.277		29.1	0.06	No	Negligible risk	—
			1.92 × 5	8.555		58.2	0.13	No	Negligible risk	—
			0.96 × 11	7.986		54.3	0.12	No	Negligible risk	—
			1.92 × 11	15.971		108.6	0.24	No	Negligible risk	—
1000	68.7	Herbivore	0.96 × 2	1.748	166	290.2	0.64	No	Negligible risk	—
			1.92 × 2	3.495		580.2	1.29	Yes	0.08	—
			0.96 × 3	2.617		434.4	0.97	No	Negligible risk	—
			1.92 × 3	4.797		796.3	1.77	Yes	0.11	No
			0.96 × 5	4.277		710.0	1.58	Yes	0.09	No
			1.92 × 5	8.555		1420.1	3.16	Yes	0.19	No
			0.96 × 11	7.986		1325.7	2.95	Yes	0.18	No

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site (6% Spray drift)	Off-Site LOC Exceeded
			1.92 × 11	15.971		2651.2	5.89	Yes	0.35	No

AR= Application Rate kg a.i./ha
CAR = Cumulative Application Rate taking into consideration the foliar half-life (kg a.i./ha).
FF = Feeding Factor = Proportion body weight consumed per day × EEC nomogram
EEC nomogram value from guidance manual.
EDE = FF × CAR
On-Site RQ = FF × CAR
Off-Site RQ = FF × (CAR × 6%)
NR = Negligible Risk (Spray drift (off-site) risk assessment is not required).

Table 5 Risk Assessment for Terrestrial Organisms (I): Reproductive Risk to Mammals from Consumption of Dodemorph-Acetate in Contaminated Food

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site	Off-Site LOC Exceeded
15	2.2	Insectivore	0.96 × 2	1.748	28	48.9	2.33	Yes	0.14	No
			1.92 × 2	3.495		97.9	4.66	Yes	0.28	No
			0.96 × 3	2.617		73.3	3.49	Yes	0.21	No
			1.92 × 3	4.797		134.3	6.40	Yes	0.38	No
			0.96 × 5	4.277		119.8	5.70	Yes	0.34	No
			1.92 × 5	8.555		239.5	11.41	Yes	0.68	No
			0.96 × 11	7.986		223.6	10.65	Yes	0.64	No
			1.92 × 11	15.971		447.2	21.29	Yes	1.28	Yes
		Granivore	0.96 × 2	1.748	7.3	12.8	0.61	No	NR	—
			1.92 × 2	3.495		25.5	1.21	Yes	0.07	No
			0.96 × 3	2.617		19.1	0.91	No	Negligible risk	—
			1.92 × 3	4.797		35.0	1.67	Yes	0.10	No
			0.96 × 5	4.277		31.2	1.49	Yes	0.09	No
			1.92 × 5	8.555		62.5	2.97	Yes	0.18	No
			0.96 × 11	7.986		58.3	2.78	Yes	0.17	No
			1.92 × 11	15.971		116.6	5.55	Yes	0.33	No
15	2.2	Frugivore	0.96 × 2	1.748	15	26.2	1.25	Yes	0.07	No
			1.92 × 2	3.495		52.4	2.50	Yes	0.15	No
			0.96 × 3	2.617		39.3	1.87	Yes	0.11	No
			1.92 × 3	4.797		72.0	3.43	Yes	0.21	No
			0.96 × 5	4.277		64.2	3.06	Yes	0.18	No
			1.92 × 5	8.555		128.3	6.11	Yes	0.37	No
			0.96 × 11	7.986		119.8	5.70	Yes	0.34	No
			1.92 × 11	15.971		239.6	11.41	Yes	0.68	No
35	4.5	Insectivore	0.96 × 2	1.748	25	43.7	2.08	Yes	0.12	No
			1.92 × 2	3.495		87.4	4.16	Yes	0.25	No
			0.96 × 3	2.617		65.4	3.12	Yes	0.19	No
			1.92 × 3	4.797		119.9	5.71	Yes	0.34	No
			0.96 × 5	4.277		106.9	5.09	Yes	0.31	No
			1.92 × 5	8.555		213.9	10.18	Yes	0.61	No
			0.96 × 11	7.986		199.7	9.51	Yes	0.57	No
			1.92 × 11	15.971		399.3	19.01	Yes	1.14	Yes

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site	Off-Site LOC Exceeded
		Granivore	0.96 × 2	1.748	6.4	11.2	0.53	No	Negligible risk	—
			1.92 × 2	3.495		22.4	1.07	Yes	0.06	No
			0.96 × 3	2.617		16.7	0.80	No	Negligible risk	—
			1.92 × 3	4.797		30.7	1.46	Yes	0.09	No
			0.96 × 5	4.277		27.4	1.30	Yes	0.08	No
			1.92 × 5	8.555		54.8	2.61	Yes	0.16	No
			0.96 × 11	7.986		51.1	2.43	Yes	0.15	No
			1.92 × 11	15.971		102.2	4.87	Yes	0.29	No
		Frugivore	0.96 × 2	1.748	13	22.7	1.08	Yes	0.06	No
			1.92 × 2	3.495		45.4	2.16	Yes	0.13	No
			0.96 × 3	2.617		34.0	1.62	Yes	0.10	No
			1.92 × 3	4.797		62.4	2.97	Yes	0.18	No
			0.96 × 5	4.277		55.6	2.65	Yes	0.16	No
			1.92 × 5	8.555		111.2	5.30	Yes	0.32	No
			0.96 × 11	7.986		103.8	2.94	Yes	0.30	No
			1.92 × 11	15.971		207.6	9.89	Yes	0.59	No
		Herbivore	0.96 × 2	1.748	311	543.6	25.89	Yes	1.55	Yes
			1.92 × 2	3.495		1086.9	51.76	Yes	3.11	Yes
			0.96 × 3	2.617		813.9	38.76	Yes	2.33	Yes
			1.92 × 3	4.797		1491.9	71.04	Yes	4.26	Yes
			0.96 × 5	4.277		1330.1	63.34	Yes	3.80	Yes
			1.92 × 5	8.555		2660.6	126.70	Yes	7.60	Yes
			0.96 × 11	7.986		2483.6	118.27	Yes	7.10	Yes
			1.92 × 11	15.971		4967.0	236.52	Yes	14.19	Yes
1000	68.7	Insectivore	0.96 × 2	1.748	3.2	5.6	0.27	No	Negligible risk	—
			1.92 × 2	3.495		11.2	0.53	No	Negligible risk	—
			0.96 × 3	2.617		8.4	0.40	No	Negligible risk	—
			1.92 × 3	4.797		15.4	0.73	No	Negligible risk	—
			0.96 × 5	4.277		13.7	0.65	No	Negligible risk	—
			1.92 × 5	8.555		27.4	1.30	Yes	0.08	No
			0.96 × 11	7.986		25.6	1.22	Yes	0.07	No

Body Weight (g)	FIR g dw diet/d	Food Guild	AR × Number Application kg a.i./ha	CAR kg a.i./ha	FF	EDE mg a.i./kg bw/d	Acute RQ In-Field	In-Field LOC Exceeded	Acute RQ Off-Site	Off-Site LOC Exceeded
			1.92 × 11	15.971		51.1	2.43	Yes	0.15	No
		Granivore	0.96 × 2	1.748	3.4	5.9	0.28	No	Negligible risk	—
			1.92 × 2	3.495		11.9	0.57	No	Negligible risk	—
			0.96 × 3	2.617		8.9	0.42	No	Negligible risk	—
			1.92 × 3	4.797		16.3	0.78	No	Negligible risk	—
			0.96 × 5	4.277		14.5	0.69	No	Negligible risk	—
			1.92 × 5	8.555		29.1	1.39	Yes	0.08	No
			0.96 × 11	7.986		27.2	1.29	Yes	0.08	No
			1.92 × 11	15.971		54.3	2.59	Yes	0.16	No
1000	68.7	Frugivore	0.96 × 2	1.748	6.8	11.9	0.57	No	Negligible risk	—
			1.92 × 2	3.495		23.8	1.13	Yes	0.07	No
			0.96 × 3	2.617		17.8	0.85	No	Negligible risk	—
			1.92 × 3	4.797		32.6	1.55	Yes	0.09	No
			0.96 × 5	4.277		29.1	1.38	Yes	0.08	No
			1.92 × 5	8.555		58.2	2.77	Yes	0.17	No
			0.96 × 11	7.986		54.3	2.59	Yes	0.16	No
			1.92 × 11	15.971		108.6	5.17	Yes	0.31	No
		Herbivore	0.96 × 2	1.748	166	290.2	13.82	Yes	0.83	No
			1.92 × 2	3.495		580.2	27.63	Yes	1.66	Yes
			0.96 × 3	2.617		434.4	20.69	Yes	1.24	Yes
			1.92 × 3	4.797		796.3	37.92	Yes	2.28	Yes
			0.96 × 5	4.277		710.0	33.81	Yes	2.03	Yes
			1.92 × 5	8.555		1420.1	67.63	Yes	4.06	Yes
			0.96 × 11	7.986		1325.7	63.13	Yes	3.79	Yes
			1.92 × 11	15.971		2651.2	126.25	Yes	7.57	Yes

AR= Application Rate kg a.i./ha
CAR = Cumulative Application Rate taking into consideration the foliar half-life (kg a.i./ha).
FF = Feeding Factor = proportion body weight consumed per day × EEC nomogram
EEC nomogram value from Guidance manual.
EDE = FF × CAR
On-Site RQ = FF × CAR
Off-Site RQ = FF × (CAR × 6%)
NR = Negligible Risk (Therefore, spray drift risk assessment is not required).

Table 6 Risk Assessment for Terrestrial Organisms (VI): Screening Level Risk Assessment for Honeybees for Foliar Applications of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Acute RQ = Cumulative Application Rate / Contact LC_{50}*	LOC (RQ = 1)
0.96 × 2	1.748	0.01	Not exceeded
1.92 × 2	3.495	0.02	Not exceeded
0.96 × 3	2.617	0.01	Not exceeded
1.92 × 3	4.797	0.02	Not exceeded
0.96 × 5	4.277	0.02	Not exceeded
1.92 × 5	8.555	0.04	Not exceeded
0.96 × 11	7.986	0.04	Not exceeded
1.92 × 11	15.971	0.08	Not exceeded

* Contact LC_{50} (kg a.i./ha) = LC_{50} (µg a.i./bee) × 1.12 = 179.6 µg a.i./bee × 1.12 = 201.15 kg a.i./ha. (Atkins et al, 1981; Atkins et al, 1975). LC50 = 179.6 µg a.i./bee based on contact exposure.

Table 7 Risk Assessment for Terrestrial Organisms (VII): Screening Level Risk Assessment for Beneficial Arthropods for Foliar Applications of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Acute RQ = Cumulative Application Rate / Contact LC_{50}*	LOC (RQ = 1)
0.96 × 2	1.748	7.05	Exceeded
1.92 × 2	3.495	14.09	Exceeded
0.96 × 3	2.617	10.55	Exceeded
1.92 × 3	4.797	19.34	Exceeded
0.96 × 5	4.277	17.25	Exceeded
1.92 × 5	8.555	34.50	Exceeded
0.96 × 11	7.986	32.20	Exceeded
1.92 × 11	15.971	64.40	Exceeded

* Toxicity Endpoint contact 48 hours LC_{50} = 0.2484 kg a.i./ha Parasitoid *Aphidius rhopalosiphi.*

Table 8 Risk Assessment for Terrestrial Organisms (VIII): Risk Assessment for Beneficial Arthropods From 6% Spray Drift (ASAE Medium Droplet Size) for Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate × 6% kg a.i./ha	Acute RQ = Cumulative Application Rate / Contact LC_{50}*	LOC (RQ =1)
0.96 × 2	0.105	0.42	Not exceeded
1.92 × 2	0.210	0.85	Not exceeded
0.96 × 3	0.157	0.63	Not exceeded
1.92 × 3	0.288	1.16	Exceeded
0.96 × 5	0.257	1.03	Exceeded
1.92 × 5	0.513	2.06	Exceeded
0.96 × 11	0.479	1.93	Exceeded
1.92 × 11	0.958	3.86	Exceeded

* Toxicity Endpoint contact 48 hours LC_{50} = 0.2484 kg a.i./ha Parasitoid *Aphidius rhopalosiphi*.

Table 9 Risk Assessment for Terrestrial Organisms (IX): Screening Level Acute Risk to Earthworms (*Eisenia foetida*) from Exposure to Dodemorph-Acetate in Soil

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	EEC mg a.i./kg soil	Acute RQ = EEC/0.5 EC_{50}*	LOC (RQ =1)
0.96 × 2	1.83	0.813	>0.01	Not exceeded
1.92 × 2	3.67	1.631	>0.01	Not exceeded
0.96 × 3	2.75	1.222	>0.01	Not exceeded
1.92 × 3	5.50	2.444	>0.01	Not exceeded
0.96 × 5	4.54	2.018	>0.01	Not exceeded
1.92 × 5	9.08	4.013	0.01	Not exceeded
0.96 × 11	9.20	4.089	0.01	Not exceeded
1.92 × 11	18.40	8.178	0.02	Not exceeded

* 0.5 × LC_{50} = 500 mg/kg dry soil. Mortality and biomass *Eisenia foetida*.

Table 10 Risk Assessment of Aquatic Organisms (I): Screening Level Acute Risk to Freshwater Fish from Application of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC Direct Overspray, mg a.i./L	Acute RQ EEC/0.1 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	80	0.224	0.74	Not exceeded
1.92 × 2	3.58	80	0.448	1.47	Exceeded
0.96 × 3	2.69	80	0.336	1.11	Exceeded
1.92 × 3	5.37	80	0.671	2.21	Exceeded
0.96 × 5	4.41	80	0.551	1.81	Exceeded
1.92 × 5	8.83	80	1.104	3.63	Exceeded
0.96 × 11	8.60	80	1.075	3.54	Exceeded
1.92 × 11	17.20	80	2.150	7.07	Exceeded

* 0.1 × LC_{50} = 0.304 mg a.i./L. Toxicity Endpoint rainbow trout (*Oncorhynchus mykiss*) 96 hours LC_{50} = 3.04 mg a.i./L.

Table 11 Risk Assessment of Aquatic Organisms (II): Acute Risk to Freshwater Fish from 6% Spray Drift (ASAE Medium Droplet Size) of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC × 6% Spray Drift, mg a.i./L	Acute RQ EEC/0.1 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	80	0.0134	0.04	Not exceeded
1.92 × 2	3.58	80	0.0267	0.09	Not exceeded
0.96 × 3	2.69	80	0.0202	0.07	Not exceeded
1.92 × 3	5.37	80	0.0403	0.13	Not exceeded
0.96 × 5	4.41	80	0.0331	0.11	Not exceeded
1.92 × 5	8.83	80	0.0662	0.22	Not exceeded
0.96 × 11	8.60	80	0.0645	0.21	Not exceeded
1.92 × 11	17.20	80	0.1290	0.42	Not exceeded

* 0.1 × LC_{50} = 0.304 mg a.i./L. Toxicity Endpoint rainbow trout (*Oncorhynchus mykiss*) 96 hours LC_{50} = 3.04 mg a.i./L.

Table 12 Risk Assessment of Aquatic Organisms (III): Screening Level Acute Risk to Freshwater Invertebrates from Application of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC Direct Overspray, mg a.i./L	Acute RQ EEC/0.5 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	80	0.224	0.25	Not exceeded
1.92 × 2	3.58	80	0.448	0.50	Not exceeded
0.96 × 3	2.69	80	0.336	0.37	Not exceeded
1.92 × 3	5.37	80	0.671	0.75	Not exceeded
0.96 × 5	4.41	80	0.551	0.61	Not exceeded
1.92 × 5	8.83	80	1.104	1.23	Exceeded
0.96 × 11	8.60	80	1.075	1.19	Exceeded
1.92 × 11	17.20	80	2.150	2.39	Exceeded

* Toxicity Endpoint 0.5 × LC_{50} = 0.9 mg a.i./L. Toxicity Endpoint 48 hours LC_{50} = 1.8 mg a.i./L *Daphnia magna.*

Table 13 Risk Assessment of Aquatic Organisms (IV): Acute Risk to Freshwater Invertebrates from 6% Spray Drift (ASAE Medium Droplet Size) of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC × 6% Spray Drift mg a.i./L	Acute RQ EEC/0.5 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	80	0.0134	Negligible Risk	—
1.92 × 2	3.58	80	0.0267	Negligible Risk	—
0.96 × 3	2.69	80	0.0202	Negligible Risk	—
1.92 × 3	5.37	80	0.0403	Negligible Risk	—
0.96 × 5	4.41	80	0.0331	Negligible Risk	—
1.92 × 5	8.83	80	0.0662	0.07	Not exceeded
0.96 × 11	8.60	80	0.0645	0.07	Not exceeded
1.92 × 11	17.20	80	0.1290	0.14	Not exceeded

* Toxicity Endpoint 0.5 × LC_{50} = 0.9 mg a.i./L. Toxicity Endpoint 48 hours LC_{50} = 1.8 mg a.i./L *Daphnia magna.*

Table 14 Risk Assessment of Aquatic Organisms (V): Screening Level Chronic Risk to Freshwater Invertebrates from Application of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC Direct Overspray, mg a.i./L	Chronic RQ EEC/NOEC*	LOC (RQ =1)
0.96 × 2	1.79	80	0.224	0.38	Not exceeded
1.92 × 2	3.58	80	0.448	0.76	Not exceeded
0.96 × 3	2.69	80	0.336	0.57	Not exceeded
1.92 × 3	5.37	80	0.671	1.14	Exceeded
0.96 × 5	4.41	80	0.551	0.93	Not exceeded
1.92 × 5	8.83	80	1.104	1.87	Exceeded
0.96 × 11	8.60	80	1.075	1.82	Exceeded
1.92 × 11	17.20	80	2.150	3.64	Exceeded

* Toxicity Endpoint 21 days NOEC = 0.59 mg a.i./L *Daphnia magna.*

Table 15 Risk Assessment of Aquatic Organisms (VI): Chronic Risk to Freshwater Invertebrates from 6% Spray Drift of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC × 6% Spray Drift mg a.i./L	Chronic RQ EEC/NOEC*	LOC (RQ =1)
0.96 × 2	1.79	80	0.0134	Negligible Risk	—
1.92 × 2	3.58	80	0.0267	Negligible Risk	—
0.96 × 3	2.69	80	0.0202	Negligible Risk	—
1.92 × 3	5.37	80	0.0403	0.07	Not exceeded
0.96 × 5	4.41	80	0.0331	Negligible Risk	—
1.92 × 5	8.83	80	0.0662	0.11	Not exceeded
0.96 × 11	8.60	80	0.0645	0.11	Not exceeded
1.92 × 11	17.20	80	0.1290	0.22	Not exceeded

* Toxicity Endpoint 21 days NOEC = 0.59 mg a.i./L *Daphnia magna.*

Table 16 Risk Assessment of Aquatic Organisms (VII): Screening Level Acute Risk to Amphibians from Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC Direct Overspray, mg a.i./L	Acute RQ EEC/0.1 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	15	1.193	3.92	Exceeded
1.92 × 2	3.58	15	2.387	7.85	Exceeded
0.96 × 3	2.69	15	1.793	5.90	Exceeded
1.92 × 3	5.37	15	3.580	11.78	Exceeded
0.96 × 5	4.41	15	2.940	9.67	Exceeded
1.92 × 5	8.83	15	5.887	19.37	Exceeded
0.96 × 11	8.60	15	5.733	18.86	Exceeded
1.92 × 11	17.20	15	11.467	37.72	Exceeded

* Toxicity Endpoint 0.1 × LC_{50} = 0.304 mg a.i./L. Toxicity Endpoint rainbow trout (*Oncorhynchus mykiss*) 96 hours LC_{50} = 3.04 mg a.i./L.

Table 17 Risk Assessment of Aquatic Organisms (VIII): Acute Risk to Amphibians from 6% Spray Drift (ASAE Medium Droplet Size) of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC × 6% Spray Drift mg a.i./L	Acute RQ EEC/0.1 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	15	0.0716	0.24	Not exceeded
1.92 × 2	3.58	15	0.1432	0.47	Not exceeded
0.96 × 3	2.69	15	0.1076	0.35	Not exceeded
1.92 × 3	5.37	15	0.2148	0.71	Not exceeded
0.96 × 5	4.41	15	0.1764	0.58	Not exceeded
1.92 × 5	8.83	15	0.3532	1.16	Exceeded
0.96 × 11	8.60	15	0.3440	1.13	Exceeded
1.92 × 11	17.20	15	0.6880	2.26	Exceeded

* Toxicity Endpoint 0.1 × LC_{50} = 0.304 mg a.i./L. Toxicity Endpoint rainbow trout (*Oncorhynchus mykiss*) 96 hours LC_{50} = 3.04 mg a.i./L.

Table 18 Risk Assessment of Aquatic Organisms (IX): Screening Level Acute Risk to Algae from Application of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC Direct Overspray, mg a.i./L	Acute RQ EEC/0.5 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	80	0.224	0.41	Not exceeded
1.92 × 2	3.58	80	0.448	0.81	Not exceeded
0.96 × 3	2.69	80	0.336	0.61	Not exceeded
1.92 × 3	5.37	80	0.671	1.22	Exceeded
0.96 × 5	4.41	80	0.551	1.00	Exceeded
1.92 × 5	8.83	80	1.104	2.01	Exceeded
0.96 × 11	8.60	80	1.075	1.95	Exceeded
1.92 × 11	17.20	80	2.150	3.91	Exceeded

* Toxicity Endpoint 0.5 × LC_{50} = 0.55 mg a.i./L. Toxicity Endpoint 72 hours EC_{50} growth rate = 1.1 mg a.i./L green algae (*Selenastrum capricornutum*)

Table 19 Risk Assessment of Aquatic Organisms (X): Risk to Algae from 6% Spray Drift (ASAE Medium Droplet Size) of Dodemorph-Acetate

Application Rate × Number of Applications kg a.i./ha	Cumulative Application Rate kg a.i./ha	Water Depth cm	EEC × 6% Spray Drift mg a.i./L	Acute RQ EEC/0.5 × LC_{50}*	LOC (RQ =1)
0.96 × 2	1.79	80	0.0134	Negligible Risk	—
1.92 × 2	3.58	80	0.0267	Negligible Risk	—
0.96 × 3	2.69	80	0.0202	Negligible Risk	—
1.92 × 3	5.37	80	0.0403	0.07	Not exceeded
0.96 × 5	4.41	80	0.0331	0.06	Not exceeded
1.92 × 5	8.83	80	0.0662	0.12	Not exceeded
0.96 × 11	8.60	80	0.0645	0.12	Not exceeded
1.92 × 11	17.20	80	0.1290	0.23	Not exceeded

* Toxicity Endpoint 0.5 × LC_{50} = 0.55 mg a.i./L. Toxicity Endpoint 72 hours EC_{50} growth rate = 1.1 mg a.i./L green algae (*Selenastrum capricornutum*)

Table 20 Refined Risk Assessment on Non-Target Species (I): Refined Acute Risk to Freshwater Fish from Dodemorph-Acetate in Runoff

Application Rate × Number of Applications kg a.i./ha	Water Depth cm	EEC 96 h Runoff, mg a.i./L	Acute RQ EEC/0.1 × LC_{50}*	LOC (RQ =1)
1.92 × 3	80	0.034	0.11	Not exceeded

* 0.1 × LC_{50} = 0.304 mg a.i./L. Toxicity Endpoint rainbow trout (*Oncorhynchus mykiss*) 96 hours LC_{50} = 3.04 mg a.i./L.

Table 21 Refined Risk Assessment on Non-Target Species (II): Refined Acute Risk to Freshwater Aquatic Invertebrates from Dodemorph-Acetate in Runoff

Application Rate × Number of Applications kg a.i./ha	Water Depth cm	EEC Peak Runoff Conc., mg a.i./L	Acute RQ EEC/0.5 × LC_{50}*	LOC (RQ =1)
1.92 × 3	80	0.0388	0.04	Not exceeded

* Toxicity Endpoint 0.5 × LC_{50} = 0.9 mg a.i./L. Toxicity Endpoint 48 hours LC_{50} = 1.8 mg a.i./L *Daphnia magna.*

Table 22 Refined Risk Assessment on Non-Target Species (III): Refined Chronic Risk to Freshwater Aquatic Invertebrates from Dodemorph-Acetate in Runoff

Application Rate × Number of Applications kg a.i./ha	Water Depth cm	EEC Yearly Runoff Conc., mg a.i./L	Chronic RQ EEC/NOEC*	LOC (RQ =1)
1.92 × 3	80	0.0302	0.05	Not exceeded

* Toxicity Endpoint 21 days NOEC = 0.59 mg a.i./L *Daphnia Magna.*

Table 23 Refined Risk Assessment on Non-Target Species (IV): Refined Acute Risk to Amphibians from Dodemorph-Acetate in Runoff

Application Rate × Number of Applications kg a.i./ha	Water Depth cm	EEC 96 h Runoff, mg a.i./L	Acute RQ EEC/0.1 × LC_{50}*	LOC (RQ =1)
1.92 × 3	15	0.0434	0.14	Not exceeded

* 0.1 × LC_{50} = 0.304 mg a.i./L. Toxicity Endpoint rainbow trout (*Oncorhynchus mykiss*) 96 hours LC_{50} = 3.04 mg a.i./L.

Table 24 Refined Risk Assessment on Non-Target Species (V): Refined Acute Risk to Algae from Dodemorph-Acetate in Runoff

Application Rate × Number of Applications kg a.i./ha	Water Depth cm	EEC 96 h Runoff, mg a.i./L	Acute RQ EEC/0.5 × LC_{50}*	LOC (RQ =1)
1.92 × 3	80	0.034	0.06	Not exceeded

* Toxicity Endpoint 0.5 × LC_{50} = 0.55 mg a.i./L. Toxicity Endpoint 72 hours EC_{50} growth rate = 1.1 mg a.i./L green algae (*Selenastrum capricornutum*)

Appendix VIII Alternative Registered Active Ingredients to Dodemorph-Acetate for Those Site-Pest Combinations of the Commercial Class Product for Which Risk Concerns Have Been Identified (Registered Alternatives According To the PMRA ELSE Database as of 20 August 2008)

Site(s)	Pest	Pest Status/Incidence[1]	Alternative Registered Active Ingredients (Resistance Management Group Number)[2,3,4]	Supported Use of Dodemorph-Acetate?[5]	Concerns from Risk Assessments?	Identification of Risk Assessment Concerns (From Preliminary Information in Risk Assessments)
Use-site Category 6: Greenhouse Non-Food Crops						
Greenhouse-grown roses, excluding the variety Tropicana (Superstar) and certain cultivars of Tropicana such as "Command Performance"	Powdery mildew	BC–present AB–present SK–no information available MB–no information available ON–present QC–present NB–no information available NS–no information available PE–no information available NL–no information available	Group 1: thiophanate-methyl[3] Group 3: propiconazole[3], triforine[3,6], myclobutanil[3] Group M1: copper from tri-basic copper sulphate[3], elemental copper[3] Group M2. Sulphur, sulphide sulphur Group M4: folpet[3] Other: QST 713 strain of *Bacillus subtilis* (biofungicide)	Y	Y	Postapplication risks to workers (see section 3.2.2)
Use-site Category 27: Ornamentals Outdoor						
Field-grown roses, excluding the variety Tropicana (Superstar) and certain cultivars of Tropicana such as "Command Performance"	Powdery mildew	BC–present AB–present SK–no information available MB–no information available ON–present QC–present NB–no information available NS–no information available PE–no information available NL–no information available	Group 1: thiophanate-methyl[3] Group 3: propiconazole[3], triforine[3,6], myclobutanil[3] Group M1: copper from tri-basic copper sulphate[3], elemental copper[3] Group M2. Sulphur, sulphide sulphur Group M4: folpet[3] Other: QST 713 strain of *Bacillus subtilis* (biofungicide)	Y	Y	Postapplication risks to workers (see section 3.2.2)

1 Information obtained from provincial crop specialists.

2 This is a list of registered options only. The PMRA does not endorse any of the options listed. A number of the listed alternative active ingredients are in the process of being re-evaluated by Health Canada, including the following active ingredient for which an information update document has been published: Sulphur (PACR2004-10). The registration status of active ingredients under re-evaluation may change pending the final regulatory decision. For additional information, consult the PMRA publications website: *www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/index-eng.php#rvd-drv*.

3 These active ingredients are under re-evaluation.

4 For greenhouse uses, labels for these older alternative products did not distinguish between field and greenhouse uses.

5 Y= use is supported by the registrant.

6 Triforine is registered as a Domestic Class product only.

Appendix IX Label Amendments for Commercial Class Products Containing Dodemorph-Acetate

The environmental risk assessment identified a potential hazard to non-target terrestrial plants. Buffer zones for field sprayers are shown in the Table below.

Add to **ENVIRONMENTAL HAZARDS:**

- **TOXIC** to aquatic organisms. Observe buffer zones specified under **DIRECTIONS FOR USE**.
- **TOXIC** to birds and small wild mammals.
- **TOXIC** to beneficial insects. It is recommended that this product not be used in areas where beneficial insects are used in IPM. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland.

Run Off

- To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil or clay.
- Avoid application when heavy rain is forecast.
- Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Volatilization

- To minimize the release of dodemorph-acetate into the environment due to volatilization, dodemorph-acetate should only be applied on cool mornings and evenings when air temperatures are 15°C or lower.

Add to **DIRECTIONS FOR USE**

General Restrictions

- **DO NOT** apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.
- **DO NOT** contaminate irrigation/drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
- **DO NOT** allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Buffer Zones:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer Zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and inter-row hooded sprayer.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Buffer Zones Required For the Protection of Aquatic Life for Dodemorph-Acetate

Method of Application	Crop	Buffer Zones (Metres) Required for the Protection of: Freshwater Habitat of Depths:	
		Less than 1 m	Greater than 1 m
Field Sprayer*	Roses	3 m	0 m

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

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